Is it justifiable to treat chronic patients by nurse specialists? : evaluation of effects on quality of care

IS IT JUSTIFIABLE TO TREAT CHRONIC PATIENTS BY NURSE SPECIALISTS?

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IS IT JUSTIFIABLE TO TREAT CHRONIC PATIENTS BY NURSE SPECIALISTS?

EVALUATION OF EFFECTS ON QUALITY OF CARE

PROEFSCHRIFT

ter verkrijging van de graad van doctor aan
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op gezag van de Rector Magnificus,
Prof. dr. A.C. Nieuwenhuijzen Kruseman,
volgens het besluit van het College van Decanen,
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Voor mijn moeder en mijn broer
Ter nagedachtenis aan mijn vader

Alterius sic altera poscit opem res et coniurat amica
Het een heeft de hulp van het ander nodig
en beiden werken vriendschappelijk samen

Horatius (Ars Poetica)

CONTENTS

CHAPTER 1

General introduction

INTRODUCTION

This dissertation focuses on the effects on quality of care for patients with a chronic disease when the nurse specialist performs the central role in care delivery. Chronic diseases as a group are rather heterogeneous with differences in aetiology and symptoms, as well as in the possibilities for their management. Nevertheless, chronic diseases are defined as 'all impairments or deviations from normal which have one or more of the following characteristics: are permanent, leave residual disability, are caused by non-reversible pathological alteration, require special training of the patient for rehabilitation, may be expected to require a long period of supervision, observation, or care' (Mayo, 1956). This definition thus distinguishes chronic diseases from acute and sub-acute episodes of illness.

Existing health care systems do not adequately address the specific needs and problems of people with a chronic disease. With the emphasis on diagnosis, ruling out serious disease, and curative or symptom-relieving treatments, health care systems are organised to respond to the acute and urgent needs of patients. Physical, psychological, and social factors need to be included and integrated when caring for chronically ill people (Spreeuwenberg, 1994). Caregivers have to act more like initiators and less like responders so that patients receive preventive interventions, systematic assessments, education, psychosocial support, counselling, and are followed-up. In addition, patients have to be encouraged to perform self-care tasks (Wagner et al., 1996).

The difficulty of managing chronic disease in a health care system largely oriented to the management of acute episodes of illness is one reason that has prompted the development of alternative disease management systems that address the unique needs of patients with chronic diseases. Another is the increasing prevalence of chronically ill patients as well as the associated costs of treatment and care (Anonymous, 1997). A review of the literature on the management of chronic diseases identified similarities among organised efforts that improve patient outcomes and grouped them under five headings (Wagner et al., 1996):

- the use of explicit guidelines based on evidence;
- the reorganisation of the practice to meet the needs of patients requiring more time, a broad array of resources, and more systematic follow-up;
- systematic attention to the information, behaviour change, and psychosocial needs of patients;
- ready access to necessary expertise;
- supportive information systems.

At the same time as presenting these characteristics as 'a useful starting point for designing evaluation, research projects, and innovation in chronic illness care' (Wagner et al., 1996), the authors urged for 'appropriately targeted health services research' to 'influence the design of medical care for patients with ongoing health

needs' (Wagner, 1997). Disease management can be regarded as a systematic, population-based approach in which health care professionals work together in a co-ordinated and co-operative manner to effect an optimal outcome for a particular patient with a particular disease throughout the entire continuum of care (Epstein & Sherwood, 1996).

In the Netherlands the development of a policy of care for chronically ill started in 1991 with the appearance of a white paper entitled 'Policy for the chronically ill, don't keep chronic patients out of it' (Ministerie WVC, 1991). Three objectives were set: to promote the effective and efficient approach of chronic diseases and their consequences, to stimulate a situation in which people with a chronic disease experience improved quality of life, and to promote a liveable societal climate for chronically ill people. With regard to the management of the care for chronic diseases, poor co-ordination between need and supply of care was identified (Ministerie WVC, 1991).

Concurrently with the policy papers about chronic care delivery, the National Council of Public Health (1989), an advisory board of the Dutch government, published a report about substitution in health care. To control the costs and to increase the efficiency of care, the message was to transfer tasks or functions and the accompanying responsibility to the lowest level of expertise and competence as possible in a justified way. Today it is believed that medicine, nursing, and allied health professionals are required to provide integrated chronic care in an inter-professional context that supports specialisation, rationalisation, maximisation, and avoids duplication (Leathard et al., 1994).

Interdisciplinary teamwork: substitution and 'transmurale zorg'

In an exploration of the development of interdisciplinary practice, McCallin (2001) found that the literature on inter-professional practice is sparse. Current organisation theory derived from the industry suggests that the quality of the product, and the efficiency of production, are dependent on successful teamwork (Andreason et al., 1995; McKenna, 1995). With the introduction of total patient care in the 1990s, the emphasis moved to interdisciplinary teamwork, as health professionals were forced to recognise the need for different professional contributions to patient care in the restructured workplace (Stein et al., 1990). It became apparent that a one-to-one relationship between physician and patient was unlikely to be sufficient to maintain health or minimise disability especially for chronically ill persons (Vinicor, 1995).

The team approach required for delivering care to the chronically ill consists of physicians and non-physicians working together (Yawn, 2000). Traditional inter-professional interactions between doctors and nurses are challenged while boundaries shift with this approach (Hopkins et al., 1996; Kernick & Scott, 2002).

Tasks or functions performed by nurses on the boundaries with physicians can assume different forms (Starfield, 1992):

- supplementary: tasks or functions that could be done, albeit inefficiently, by physicians;
- complementary: tasks or functions for which physicians often have neither the skills nor the time to do well;
- substitute: tasks or functions that are traditionally performed by physicians.

When tasks or functions are transferred between caregivers within one level of expertise, the substitution is horizontal, while the transfer of tasks or functions between caregivers of different levels of expertise is referred to as vertical substitution (Spreeuwenberg, 1994). When these two forms of substitution simultaneously take place, diagonal substitution occurs.

In the Netherlands substitution and 'transmurale zorg' were introduced as ways of enlarging the co-operation and co-ordination in care as well as to improve the effectiveness and efficiency of care (Commissie Modernisering Curatieve Zorg, 1994; NRV, 1989). 'Transmurale zorg' refers to care ('zorg') given 'through the walls' of the segmented Dutch health care system and is tailored to meet patient's needs, being provided on the basis of agreements on co-operation, harmony, and direction between general and specialised caregivers, where responsibilities are borne both individually and commonly (NRV/CVZ, 1995). The approach overlaps with the concepts of shared care (UK) and integrated care (US) (Van der Linden, 1997). And although 'transmurale zorg' has been translated in transmural care by Dutch authors, here this concept is indicated as integrated care.

Integrated care in the Netherlands turns to be a concept which consists of a wide and varied range of health services (Persoon et al., 1996). An inventory of integrated care services as mentioned in several sources between 1990 and 1996 identified 352 services which were categorised in three basic forms: integrated care delivered by specialised hospital and general primary care together; integrated care delivered by generalist primary care professionals who are supported by specialist hospital professionals; and integrated care during admission to and discharge from a specialised care organisation, delivered by generalist primary care professionals. Integrated care services are most often aimed at chronically ill people. Integrated care is found to be an interdisciplinary concept with nurses being the occupational group most often involved (Persoon et al., 1996).

Acknowledging the pivotal role of nurses in the care for chronic patients as well as the differences in health care systems, Temmink (2000) searched the literature for substitution-related nursing innovations directed at chronic patients. She reported three kinds of innovations: advanced nursing practice, hospital-at-home care, and integrated care setting. The first two kinds were found in primary care oriented countries, while an ongoing process of integration between generalist and specialist health

care services in both primary and secondary care oriented countries was reported (Temmink, 2000).

Integrated care for chronically ill in the region of Maastricht and allied regions

In 1994 the Maastricht University Hospital decided to structure and expand activities in integrated care. It was decided to place the organisation of these activities in the existing Diagnostic and Co-ordinating Centre. The improvement of co-operation between general practitioners (GPs) and medical specialists was already one of the main tasks of this centre. Recently, this centre has become the unit for integrated care of the Maastricht University Hospital (Pop & Spreeuwenberg, 1998).

To control costs and to ascertain high quality care against the background of the predicted rise in the number of chronically ill, tasks were transferred from medical specialists to GPs. The joint consultation session between GPs and orthopaedic surgeons was the first integrated care project with care delivery being based on horizontal substitution (Vierhout et al., 1995). However, with the continual extension of job responsibilities of the GP (Van Duijn & Mentink, 1998), the idea was launched to transfer tasks or functions from physician to nurse specialist in the care for patients with stable diabetes type 2, stable chronic obstructive pulmonary disease (COPD), or stable rheumatoid arthritis (RA).

In particular, for patients with a chronic disease in a stable phase, it was believed that the nurse specialist could operate as the main care provider and thus substitute for the physician. In the phase of stability attention should be on the person with the disease – nursing's orientation – as opposed to the disease – medicine's orientation (Taylor, 1995). However, defining stability for RA is not as straightforward as for diabetes type 2 or COPD. To describe the disease status and the efficacy of treatment in type 2 diabetic patients, glycosylated haemoglobin (HbA_{1c}) is used as main parameter, while in COPD the forced expiratory volume in one second (FEV_1) is used for this purpose. With regard to RA, there is no such internationally accepted parameter to define stability. Consensus about which endpoints to measure when assessing disease activity of RA exists, but the definition of disease stability still varies. It was agreed that in the case of RA, first the applicability of criteria to assess stability had to be established before introducing a substitution-based model for patients with stable RA.

Supported by research findings from studies outside the Netherlands (Charlton et al., 1991; Foulkes et al., 1989; Hill et al., 1994; MacKinnon et al., 1989; Ramsay et al., 1982), a team approach in the care of patients with stable diabetes type 2 or stable COPD was proposed in the form of a care-network in the first half of 1996 in the region of Maastricht. A variety of health professionals involved in diabetes care agreed upon the delivery of care in an interactive and interdependent way with inter-profes-

sional substitution between medical specialist and nurse specialist. Moreover, in the diabetes care-network patients seen quarterly by the medical specialist in the outpatient department of the hospital are transferred to the nurse specialist and receive three quarterly consultations in the practice of their GP. The nurse specialist and the GP hold regular appointments to discuss the management of individual patients. The medical specialist still performs one annual consultation in the hospital. Tasks, activities, and targets of care delivery are formulated in a protocol between all involved parties. Besides the medical specialists, GPs, and nurse specialists, the parties involved are: patients, dieticians, the 'Green Cross' home care agency, co-ordinators of the care-network in Maastricht and of a broader network for the delivery of care to chronically ill patients ('Synchron').

With the availability of two diabetes nurses employed by the university hospital Maastricht, the care-network for patients with stable diabetes type 2 was introduced first in the region of Maastricht. The care-network was partly adopted by a co-operation of a primary care health centre (Gezondheidscentrum Withuis) and the general hospital in Venlo (St. Maartens Gasthuis) for patients with stable diabetes type 2 looked after in the primary care setting. The care for these patients was transferred from GP to nurse specialist. A similar care-network was also partly adopted by pulmonologists and nurse specialists in the hospital of Alkmaar (Medisch Centrum Alkmaar) in the care for patients with stable COPD, by transferring care from pulmonologist to nurse specialist in the outpatient department of the hospital. At the same time nurses specialised in COPD were introduced in the region of Maastricht, fulfilling a complementary function to GPs by screening patients at risk for asthma or COPD.

RESEARCH

Original model of research

The introduction of the care-network for people with stable diabetes type 2 or COPD was accompanied by scientific evaluation research. Moreover, it was decided to separately perform a process evaluation and an effect evaluation to assess:

- whether the care-network contributes to the aim of providing care for patients with stable diabetes type 2 or COPD as close as possible to their own environment and to the aim of substitution of the nurse specialist for the physician (process evaluation);
- which factors promote or hamper the above mentioned contributions (process evaluation);
- the effects on quality of care of the network in terms of patient outcomes (effect evaluation);

– the comparability of the findings from the care-networks across diseases (both evaluations).

The design of the part of the research as presented in this dissertation, the effect evaluation, was influenced by several factors, in particular by the decision to consider patients with diabetes type 2, COPD, and RA. These diseases were chosen because of the predicted rise in the number of patients, the large variation in practice, the potential to standardise the delivery of care, the high aggregate costs of which a large portion is due to drug therapy, the availability of measurable health outcomes, and the potential gains in health outcomes and cost savings. In addition, from the start it was recognised that the care-network would be refined and adjusted in daily practice. This implied that the context for research was not completely under control and that the design of the evaluation gained shape according to the specific circumstances encountered.

Before the care-network for RA could be introduced, the applicability of criteria to assess stability of RA had to be established first. With the availability of internationally accepted criteria to assess stability for diabetes type 2 and COPD, it was decided to review the literature for effects on quality of care of care-models with a central role for the nurse specialist. With regard to the care for patients with stable diabetes type 2 in the region of Maastricht, a care-network was introduced: care was referred from outpatient clinic to primary care and from medical specialist to nurse specialist – diagonal substitution. In the region of Venlo, GPs partly applied this care-network by transferring the care for stable diabetes type 2 patients within primary care from GP to nurse specialist – vertical substitution. For patients with COPD the care-network was also partly applied in the region of Alkmaar by substitution of the nurse specialist for the pulmonologist in the care for patients with stable COPD in the outpatient clinic – vertical substitution.

Based on the experiences with the nurse specialist in performing the central role in the delivery of care for patients with stable diabetes type 2 or COPD, it was decided to make use of the services of the nurse specialist in the phase of early detection. The identification of patients at risk as well as the care for patients diagnosed with COPD was organised in a way in which healthcare professionals work together in a co-ordinated and co-operative manner. This facilitated the aim to create an environment of provider accountability to achieve high quality care over several phases of the continuum of care for a patient – disease management.

Furthermore it was decided to make a strict separation between the development of the care network and the scientific evaluation to secure the independence and objectivity of the research. Finally, the evaluation of the process was distinguished from the effect evaluation, because of the divergent methods of research.

Research questions

The study presented in this dissertation tries to answer the following six questions:

1. Can low disease activity criteria using the DAS28 be applied by nurse specialists to assess the degree of disease stability in patients with RA, and are these criteria sufficiently reliable to select stable patients out of an outpatient population for enrolment in a care-network?
2. Which outcomes are identified in trials about the effectiveness and efficiency of care-network models in which the nurse specialist performs a central role and are these models effective and efficient?
3. What are the effects on quality of care when the care for patients with stable diabetes type 2 is transferred from medical specialist to nurse specialist and from outpatient clinic to general practice?
4. What are the effects on quality of care when the care for patients with stable diabetes type 2 is transferred from GP to nurse specialist within general practice?
5. What are the effects on quality of care when the care for patients with stable COPD is transferred from pulmonologist to nurse specialist within the outpatient clinic?
6. To what extent is the support offered by nurse specialists to GPs in the early detection of patients with COPD feasible?

Research question 3, 4, and 5 are regarded as the central research questions of this dissertation.

Research hypotheses

The rationale behind the care-networks mentioned or referred to in research questions 1, 2, 3, 4, and 5 is that in the care for medically stable chronic patients, physicians can allocate activities to nurse specialists, allowing the physicians to shift their attention towards managing patients with most complex problems. However, in RA the concept and definition of stability is more troublesome than in diabetes mellitus or COPD. The activity of RA cannot simply be expressed by one single parameter, and the presentation of RA may vary substantially over time between patients as well as within the same individual, considering the frequent occurrence of flares (Van Gestel et al., 1996). Although not developed for this purpose, it is hypothesised that the low disease activity criteria using the DAS28 are applicable to assess stability of RA.

Before the implementation of the care-networks in which the nurse specialist performs a central role, a search was made of the literature for trials evaluating such models on their effects on outcomes of care. The hypothesis behind the transfer of tasks from physician to nurse specialist in the care for people with a stable, chronic disease is that the quality of care generated by the nurse specialist is at least equivalent

to the quality of care performed by the physician. This hypothesis underlies research questions 3, 4, and 5.

The hypothesis behind research question 6 is that, with the nurse specialist in a complementary function to the GP, undiagnosed patients and patients at risk for COPD are detected in an early phase, thus enlarging the probability that the airway disease of these patients remains (longer) stable.

Research designs

Following from the different nature of the research questions, different designs were used to answer the questions. Research questions 3, 4, and 5 relate to the effects on quality of care in terms of patient outcomes when care is transferred from physician to nurse specialist. Ideally, these questions require a comparison of alternative interventions for outcomes with patients randomly allocated to the interventions. Randomised controlled trials reduce the likelihood of bias in determination of outcomes. While a randomised controlled trial has internal validity, it might lack external validity (Grimes & Schulz, 2002). Due to local circumstances, the randomised controlled trial could not be applied in all three main research questions.

The only setting in which the randomised controlled trial could be applied was where we studied the effects on quality of care when care was transferred from pulmonologist to the nurse specialist for outpatients with stable COPD (research question 5). Here, patients were randomly allocated to usual outpatient care by the pulmonologist or to outpatient care by the nurse specialist. The intervention in research question 3 required GPs to provide a work environment for the nurse specialist in their practice. Thus, instead of randomly allocating patients to the intervention or usual care, only patients from GPs willing to participate in the care-network could be allocated to the intervention group. Patients from GPs who preferred continuing the provision of usual care were allocated to the control group, and therefore use was made of a non-equivalent control group design (Cook & Campbell, 1979).

The setting in which research question 4 was studied did not offer the possibility to form a control group. However, with the availability of the control group of outpatients with stable diabetes type 2 from the design applied for research question 3, we applied this control group here as well. The design used to answer question 4 is called an untreated comparison group design with pretest and posttest (Cook & Campbell, 1979). Having the estimates of effects on quality of care derived from different study designs at our disposal, we were able to consider the association between methodological quality and the magnitude of the estimates.

To answer research question 1, the low disease activity criteria using the DAS28 were applied on patients with RA from the outpatient department of the university hospital Maastricht at three different moments during a 6-month period. For research

question 2, we studied the literature using Medline Express for trials about the effectiveness and efficiency of care-network models with the nurse specialist in a central role, published between 1966 and January 1999. The feasibility of the support provided by nurse specialists to GPs in the early detection of COPD – research question 6 – was assessed by measuring the airflow obstruction of patients and differentiating patients diagnosed with COPD from patients without, on the basis of known risk factors. For details about the designs applied, we refer the reader to the following chapters which all include a section in which the design is described in greater detail.

Operationalism and instrumentation

In the central research questions of this dissertation, effects on quality of care are evaluated in terms of outcomes. According to the definition of quality by Donabedian, who stated that quality is the result of assessing the structures, processes, and outcomes (Donabedian, 1966), the focus here is put on one indicator of quality of health care. The care-network in which care is transferred from physician to nurse specialist is seen as a new structure that influences the processes – what care providers do and how they provide care – and indirectly influences the outcomes – the results of care delivery for patients in terms of outcomes. Processes of care in the care-network with a central role for the nurse specialist are focus of the research by Eijkelberg et al. (2000; 2001) and will only be considered in the discussion part of this dissertation. Separation of the assessment of processes and outcomes is induced by the divergent methods of assessment, while it is acknowledged that information from both is needed to reveal the effects on quality of care when delivered in the care-network wherein the nurse specialist performs a central role.

For the purpose of this research the following definition of outcomes is used: 'states or conditions of individuals and populations attributed or attributable to antecedent health care' (Donabedian, 1992). According to Donabedian (1992), the best way to identify relevant outcomes is to ask: 'if we are successful in what we are doing, what change in patients or populations can we expect to achieve and detect?' A list of more usual outcomes pertinent to quality assessment was presented by Donabedian (1992) as well as by the UK Clearing House for Information on the Assessment of Health Services Outcomes (Long et al., 1993). Based on these classifications, a study group of the Dutch Organisation for Scientific Research (Driessen et al., 1994) presented a set of outcome-indicators with regard to the quality of care for chronically ill patients. This set is based on known objectives in the care for chronically ill people and includes survival, clinical parameters, health status, self-care behaviour, and patient satisfaction (Driessen et al., 1994). While these indicators assess the effectiveness of care, for the assessment of the efficiency of care the outcomes have to be related to the inputs.

Clinical parameters were regarded to indicate if substitution is justified. To assess whether substitution really took place, consultations with main care-providers were assessed. Self-care, knowledge and patient satisfaction were regarded as indicators for the nursing's orientation, that is attention to the patient with the disease. With the nurse specialist substituting for the physician in the care of patients with a stable chronic disease, survival was not considered as an outcome of the care-networks. General as well as disease specific instruments were applied to assess effects on clinical parameters, health status, self-care behaviour, and patient satisfaction. By measuring medical consumption, an indication for efficiency was provided. Assessing the cost-effectiveness of the care-networks was not the aim of this thesis. For details about the instruments applied we refer to the following chapters which all include a section in which the instrumentation is described in greater detail.

OUTLINE OF THIS THESIS

Chapter 2 presents the findings about the applicability of the low disease activity criteria using the DAS28 in assessing the stability of RA in outpatients. The aim of this chapter is to assess the credibility of these criteria for selecting patients with stable RA out of an outpatient population with RA for enrolment in a care-network in which consultations are transferred from rheumatologists to nurse specialists.

Chapter 3 introduces chapters 4, 5, and 6 by reviewing the literature in order to answer two questions: (1) which outcomes are identified in publications about the effectiveness and efficiency of models of care for patients with diabetes type 2 or COPD when the nurse specialist has a central role in care delivery, and (2) are these models of care effective and efficient?

The effects on quality of care when care for patients with stable diabetes type 2 is transferred from physician to nurse specialist are reported in chapters 4 and 5. Chapter 4 presents a study in the region of Maastricht where care for outpatients with stable type 2 diabetes was transferred from endocrinologist to nurse specialist and simultaneously from outpatient department to primary care. In Chapter 5 the findings of a study in the region of Venlo are presented. The study in this chapter evaluates effects on quality of care when care for patients with stable diabetes type 2 is transferred from GP to nurse specialist, both working in general practice.

Chapters 6 and 7 focus on the management of patients with COPD. Chapter 6 presents a study in the region of Alkmaar where the care for outpatients with stable COPD was transferred from pulmonologist to nurse specialist. By taking the results of the lung function measurement at the starting point, the predictive value of medical history and symptoms in the identification of patients at risk for airflow obstruction or COPD was assessed, as reported in Chapter 7. Moreover, patients who consulted their

GP for reasons unrelated to respiratory disease were assessed for their respiratory function by medical students and nurse specialists.

A summary and discussion of the main findings are presented in Chapter 8. From the results of this thesis, recommendations with regard to the structure of care for chronically ill patients and for future research are addressed.

Because chapters 2 to 7 are based on research manuscripts published in scientific journals or submitted to a journal for publication, most of the chapters are written to stand alone and some repetition will be inevitable.

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2 CHAPTER

Applying low disease activity criteria using the DAS28 to assess stability in patients with rheumatoid arthritis

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Based on paper accepted by *Annals of Rheumatic Diseases*.

ABSTRACT

This study examines whether low disease activity criteria using the DAS28 can be applied to identify a reasonable large number of patients with a stable low disease activity over a 6-month period with the ultimate intention to include these patients into a substitution based integrated care model. Also the reliability of the DAS28 for selecting stable patients out of an outpatient population was assessed.

Patients regularly seen at the rheumatology outpatient department of the university hospital Maastricht, were invited for assessment of the stability of their rheumatoid arthritis. The integrated care model was intended to provide care to patients with stable, low disease activity of rheumatoid arthritis by nurse specialists. For this, patients underwent assessments using the DAS28 at entry, three and six months later. Test-retest reliability was assessed for composing measures as well as for the DAS28.

Of the 97 outpatients included, one third (31 patients) did not complete the study. Patients with missing data were older and assessed their disease activity higher than patients with complete data. Applying the low disease activity criteria to assess stability over a period of six months (DAS28(T0)≤3.2 and DAS28(T6)-DAS28(T0)≤1.2) resulted in a proportion of patients with stable, low disease activity of rheumatoid arthritis of 39.3%. Good similarity score (ICC = 0.82) for the DAS28 was found.

The low disease activity criteria using the DAS28 seem to be applicable to select patients with stable, low disease activity of rheumatoid arthritis out of a rheumatic outpatient population.

INTRODUCTION

Recently different new models of organising care for chronic patients have been introduced to optimise the treatment of the growing number of chronically ill people in Western countries (Van der Linden, 1997). In the care for medically stable chronic patients, medical specialists can allocate activities to other health professionals, allowing them to shift their attention towards managing patients with more 'serious' problems (Jenkins-Clarke et al., 1998; Richards et al., 2000; Vrijhoef et al., 2001). Stable in this context means constant low activity of the chronic disease, i.e. without flares. These substitution-based models are believed to be better approaches to planning and delivering health care to the chronically ill (Davis et al., 2000).

In rheumatoid arthritis (RA) the concept and definition of stability is more troublesome than in chronic diseases like diabetes mellitus or chronic obstructive pulmonary disease. The activity of RA cannot be simply expressed by one single parameter and the presentation of RA may vary substantially over time between patients as well as within the same individual, considering the not infrequently occurrence of flares (Van

Gestel et al., 1996). Nevertheless, for RA too – a chronic disease for which the number of patients is predicted to rise – substitution-based models of care are gaining interest (STG 1991; Davis et al., 2000).

Disease stability is derived from measurements of disease activity, which have a central place in the management of RA, because reducing disease activity is the paradigm of treatment of RA. Measures of rheumatic disease activity can be classified as both process and outcome measures (Kirwan, 1992). Kirwan (1992) defined process as 'the abnormal physiological consequences that follow from the cause of the disease' and outcome as 'the suffering or loss of health (death, disability, discomfort, iatrogenic, economic) of the patient caused by the disease process.' Agreement on what to measure to assess disease activity in RA has been reached both in Europe (European League Against Rheumatism – EULAR– core-set) as well as in the USA (American College of Rheumatology – ACR – core-set) (Boers et al., 1995).

Notwithstanding the consensus about which endpoints to measure when assessing disease activity (both core-sets comprise process measures), the definition of rheumatic stability, as derived from subsequent measurements of rheumatic activity, still varies. Disease stability can be defined as the lack of – within certain limits–changes or fluctuations in parameters of a disease within a defined period of time. For assessing disease stability a time component has to be included in the measure: based on subsequent measures of disease activity, the degree of disease stability can be assessed.

From the EULAR core-set the so-called EULAR response criteria were derived, while based on the ACR core-set criteria for improvement have been developed. The latter define change as a difference of 20% or more in subsequent measurements of tender and swollen joint counts and a difference of 20% or more in at least three out of five remaining measures (Felson et al., 1995). The EULAR response criteria make use of a disease activity score (DAS28) derived from four measures and, in addition to change in disease activity from baseline, also takes the level of disease activity attained during follow-up into account when defining response (Van Gestel et al., 1996; Van Gestel et al., 1998). Considering these definitions within the context of assessing stability in this study also a low disease activity at baseline is necessary. Otherwise patients with severe RA are classified as having stable, low disease activity of RA and consequently not managed adequately. Thus, only the EULAR response criteria seem to allow application to assess stability although they have not originally been developed for this purpose. Besides, although the use of these criteria to include patients has been advocated before (Van Gestel et al., 1996), no study is yet known to report the results of this particular application.

This study examines whether low disease activity criteria using the DAS28 can be applied to identify a reasonable large number of patients with a stable low disease activity over a 6-month period with the ultimate intention to include these patients into a substitution based integrated care model.

MATERIALS AND METHODS

Patient selection

All patients, who were receiving care by rheumatologists at the rheumatology outpatient department of the university hospital Maastricht and known to have RA, according to the criteria of the ACR (Arnett et al., 1988), were identified.

An explanatory letter with informed consent form and postage-free envelope were mailed to patients with RA. Only those patients were invited who had been referred by general practitioners willing to have the RN in their practice in case the model would be implemented in clinical practice after completion of this feasibility study. After having given their informed consent, patients were scheduled for assessment of disease activity by a RN in the outpatient department of the hospital. Three assessments were scheduled: at entry (T0), three months (T3) and six months later (T6). Just before every assessment patients were sent a self-report form and asked to complete this on the day of assessment and to hand it in to the RN. Three months was chosen as the interval between measurements of stability because this period of time is often applied by many physicians when seeing stable chronic patients. Assessments were performed between April 1998 and February 1999.

Measures of disease activity

The number of swollen and the number of tender joints were both assessed by 28 joint counts (Prevoo et al., 1993). For this a mannequin, consisting of a stick figure drawing of a person with each joint indicated by a circle, was used. In case of a tender or swollen joint the RNs ticked the appropriate circle (range 0–28). A five-point Likert scale (1 = asymptomatic, 2 = mild, 3 = moderate, 4 = severe, 5 = very severe) was used for global assessment of disease activity by the patient (Scott et al., 1993). Blood samples were taken to determine Westergren erythrocyte sedimentation rate (ESR in mm after 1 hour). The Disease Activity Score (DAS28) was calculated using ESR, number of tender and swollen joints assessed by the nurse, and patient's global assessment of disease activity (Prevoo et al., 1995; Van Gestel et al., 1996; Van Gestel et al., 1998). This score may range from 0 to 9.3, where a DAS28 score ≤ 3.2 is considered to reflect low disease activity and a DAS28 score >5.1 high disease activity (Van Gestel et al., 1998).

Stability criteria

Applying the DAS28 to define a low and stable disease activity, patients are classified as having stable RA if at baseline the DAS28 was ≤ 3.2 (low current disease activity)

and between baseline and last post-measurement the difference in DAS28 scores was ≤1.2. This difference is two times the measurement error and is considered to be a statistically significant change in disease activity (Van Gestel et al., 1998).

Statistical analysis

Baseline comparisons between patients with and without complete data were performed with Student's t-test, Pearson chi-square and Mann-Whitney U-test. Test-retest reliability was assessed with the intraclass correlation coefficient (ICC), using the scores obtained at the three measurements (Bravo & Potvin, 1991). The findings from the application of the DAS28 assess stability were expressed as proportions.

Data processing and analyses were conducted with SPSS (Windows Release 9.0).

RESULTS

Patients

One hundred and nine patients were eligible for the study, of whom 97 gave informed consent. Reasons for not giving informed consent were lack of interest (n=4) or unknown (n=8). After giving informed consent 66 patients (68%) completed the study. The reasons for 31 patients (32%) dropping out were loss of interest (n=9) or unknown (n=22).

Comparison of groups with and without data at all measurements revealed a statistically significant difference in that older patients with missing data on average reported a higher mean score for both global assessment of disease activity and DAS28 (Table 1). The presence of data at all measurements does not imply complete data. Moreover, for 56 patients complete data were available, while for 10 patient the score on one or more variables at one or more measurements was absent.

Reliability of measurements for stability assessment

Assessment of reliability of measurements at the three measurements showed moderate ICCs (0.6–0.8) for tender and swollen joints assessed by the nurse (Table 2). Good ICCs (>0.8–0.9) were found for global assessment of disease activity, and DAS28, while very good ICC (>0.9) was found for ESR.

Table 1
Baseline characteristics of patients with all measurements and patients with missing measurements

Characteristic (mean ± sd)	Complete measurements (n=66)	Missing measurements (n=31)	p-value
Age (yrs)	62.7±12.4	68.6 ± 11.9	0.030[a]
Sex (% male)	43.9	54.8	0.316[b]
Tender joints	2.7 ± 3.2	3.9 ± 4.4 [27]	0.165[a]
Swollen joints	3.3 ± 3.1	4.1 ± 2.9 [28]	0.275[a]
ESR (mm/hr)	18.3 ± 17.0 [63]	24.5 ± 25.0 [27]	0.176[a]
Global DA[d]	3.0 ± 1.0 [62]	3.5 ± 0.9 [24]	0.035[a]
DAS28	2.9 ± 1.0 [63]	3.5 ± 1.0 [22]	0.050[c]

[ ] number of patients for whom data is used in case data was not available for whole group; [a] Student's t-test; [b] Pearson Chi-square; [c] Mann-Whitney U-test; [d] Global assessment of disease activity

Table 2
Intraclass correlation coefficient (ICC) for measurements of activity

Measurement	N	Mean ± sd			Intraclass correlation coefficient[d]	95%CI
		T0[a]	T3[b]	T6[c]		
Tender joints	65	2.8 ± 3.2	3.2 ± 3.3	3.4 ± 3.8	0.74	0.61–0.83
Swollen joints	65	3.4 ± 3.1	2.8 ± 2.9	2.7 ± 3.0	0.80	0.70–0.87
ESR (mm/hr)	60	18.6 ± 17.4	20.4 ± 19.2	22.5 ± 17.6	0.94	0.91–0.96
Global DA[e]	62	6.4 ± 1.4	6.5 ± 1.6	6.4 ± 1.7	0.86	0.79–0.91
DAS28	56	3.0 ± 1.0	3.2 ± 0.9	3.2 ± 1.1	0.82	0.72–0.89

[a] T0 measurement at start; [b] T3 measurement three months after start; [c] T6 measurement six months after start; [d] p< .001; [e] global assessment of disease activity

Table 3
Scores of patients on DAS28 at baseline, six months later, and differences between scores at baseline and six months later

T0[a]	T6 - T0	T6[b]			Total
		≤3.2	>3.2 but ≤5.1	>5.1	
≤3.2	≤1.2	18	4	0	22
	>1.2	0	4	1	5
>3.2 but ≤5.1	≤1.2	11	15	0	26
	>1.2	0	1	0	1
>5.1	≤1.2	0	0	2	2
	>1.2	0	0	0	0
Total		29	24	3	56

[a] T0 measurement at start; [b] T6 measurement six months after start

Table 4

Scores of patients on DAS28 at baseline (T0), differences between subsequent scores (T3-T0, T6-T0) and patients with stable, low disease activity of RA[#]

T0			T3-T0≤ 1.2		T3-T0≤ 0.6		T6-T0≤ 1.2		T6-T0≤ 0.6		Stable RA[#]	
	n	cum%	n	cum%	n	cum%	n	cum%	n	cum%	n	cum%
≥1.32 but <1.60	4	7.1	3	5.4	3	5.4	3	5.4	3	5.4	3	5.4
≥1.60 but <2.40	13	30.3	11	25.0	9	21.4	10	23.2	7	17.9	10	23.2
≥2.40 but <3.20	10	48.2	9	41.1	6	32.1	9	39.3	6	28.6	9	39.3
≥3.20 but <4.00	22	87.5	22	80.4	20	67.9	21	76.8	17	58.9	0	39.3
≥4.00 but <4.80	4	94.6	4	87.5	3	73.2	4	83.9	2	62.5	0	39.3
≥4.80 but <5.85	3	100.0	3	92.8	3	78.6	3	89.3	3	67.9	0	39.3

[#] DAS28(T0)≤3.2 and DAS28(T6)-DAS28(T0)≤1.2

Applying the DAS28 resulted in low disease activity in almost half (n=27; 48.2%) of the patients at baseline (Table 3). The difference in DAS28 between baseline measurement and last post-measurement was for most patients (n=50; 89.3%) under the 1.2. At T6 18 patients (32.1%) can be classified as having stable, low disease activity of RA, while 11 patients (19.6%) changed from having medium activity of RA to having low disease activity of RA.

Four patients with low disease activity of RA at baseline did not change more than 1.2 DAS28-points but had medium disease activity of RA six months after baseline measurement. Between baseline and first post measurement 92.8% did not change more than 1.2, while between baseline and last post measurement 89.3% of patients did not change more than 1.2 DAS28-points (Table 4). When the allowed change was set at 0.6 (one times the measurement error), these proportions were 78.6% and 67.9% respectively. Applying the low disease activity criteria, that is a DAS28 baseline score ≤3.2 and a difference ≤1.2 between DAS28 scores at baseline and last post-measurement, resulted in stable low disease activity of RA in 39.3% (n=22) of the patients.

DISCUSSION

The disease activity of outpatients with RA was assessed on several occasions with the ultimate intention to include these patients in an integrated care model. For this assessment, low disease activity criteria using the DAS28 were applied. The DAS28 is developed to measure a clinically relevant decrease in disease activity resulting from a treatment. In this study, however, the DAS28 was used for a different purpose, that is to assess disease stability by defining stability as 'the lack of – within certain limits – changes or fluctuations in parameters of a disease within a defined period of time,' where the 'limits' were defined by the EULAR response criteria. Without the existence of a golden standard to assess stability in RA, the findings of these study are not always unambiguous to interpret.

In this study it was found that 22 patients (39.3%) could be classified as having stable, low disease activity of RA. The defined extent of change (1.2 DAS28-points) raises an important issue. A patient with an initial DAS28 of 3.2 and 4.4 at last follow-up has, according to this change, stable RA while his/her index-score increases between first and last measurement by 37.5%. When the defined extent of change was 0.6 DAS28-points, 16 patients (28.6%) at T6 showed stable, low disease activity of RA. When applying the DAS28 baseline score at all measurements (DAS28(T0)≤3.2

and DAS28(T3)≤3.2 and DAS28(T6)≤3.2), the same 16 patients (28.6%) showed stable RA.

The result of assessing about 39.3% of patients as having stable, low disease activity of RA might be regarded as remarkable in a disease like RA. Furthermore, in the light of substituting care this finding gains importance with an increase in the number of patients with RA treated on a rheumatology outpatient department.

The interval of three months between measurements was derived from medical practice in which patients usually do not see the physician more often than four times a year. Both for establishing the optimal number of consultations for patients with stable RA, and for the purpose of stability assessment, further research into the length of the interval between measurements should be initiated.

The loss of one third of the group of patients needs attention. The patients with missing data were older, reported a higher mean DAS28 score, and higher mean global disease activity. It is conceivable to assume that these patients had more often non-stable RA. If data had been available for these non-stable patients, the ICCs would have been smaller.

With respect to the ICC, it might well be that identical scores are obtained in successive administrations, thus resulting in high value for the ICC, but that the actual units checked differ greatly. Based on the ICCs of the response criteria, a rather stable group of patients was identified.

In conclusion, this study shows the feasibility of assessing disease activity of outpatients with RA. Although developed to measure response we applied the DAS28 to assess stability, i.e. low disease activity in RA of patients for the purpose of including patients in another study. A minority of outpatients could be classified as having stable, low disease activity of RA. This finding suggests that RA is a suitable chronic disease to unfold a substitution based model of care delivery.

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3 CHAPTER

Effects on quality of care for patients with type 2 diabetes or COPD when the specialised nurse has a central role: A literature review

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Based on paper published in *Patient Education and Counseling* 2000;41:243–50.

ABSTRACT

Chronic care has to be organised in a way that care from any one caregiver is linked up to that provided by others so that disturbing gaps, contradictions and overlaps are avoided. In the search for the most effective and efficient combination of health professionals to deliver care to chronic patients, the role of the specialised nurse has become important. This article reviews a Medline search for publications about effects of models of care for patients with diabetes type 2 or COPD in which the specialised nurse has a central role. Main features of the models are identified and related to expected and statistically significant effects. In this young domain of effect evaluation ten publications met our criteria. Depending on the division of tasks between care providers improvements are seen in self-care, quality of life, patient satisfaction as well as increased medical consumption. More, methodologically suitable evaluations with the use of only valid measures are needed.

INTRODUCTION

New concepts about the care for chronically ill patients require changes in existing health care systems. The growing number of patients with a chronic disease such as diabetes mellitus or chronic obstructive pulmonary disease (COPD) leads to an increase in the costs of care. The world's diabetic population will probably have doubled from an estimated 110 million in 1994 to 221 million in 2010 (Amos et al., 1997) and despite less reliable statistics for COPD across countries, the prevalence rates of COPD are expected to increase as well (Siafakas et al., 1995).

This has resulted in pressure on the limited resources available for health care. Moreover it is recognised that the needs of chronically ill people place specific demands on health care systems. In addition to the treatment of the disease, attention for the total functioning of the sick person has to be assured. Caregivers have to be more initiators and less respondents so that patients receive preventive interventions, systematic assessments, education, psychosocial support and counseling (Wagner et al., 1996). Patients have to be encouraged to execute self-management tasks (Wagner et al., 1996). And to achieve compliance with long term care follow-up is required (Wagner et al., 1996).

The way medical care is organised at present in Western countries is to meet the acute and urgent needs of patients. However, chronically ill people need general and specialised care simultaneously. To meet the needs of chronic patients, different caregivers and patients themselves have to be involved in care. Co-ordination and continuity of care are needed so that all these parts of care and the caregivers mesh well to achieve 'tailor-made' or 'high-quality' care. This means that chronic care has to be

organised in a way that care from any one caregiver is linked up to that provided by others so that disturbing gaps, contradictions and overlaps are avoided (Van Achterberg, 1997).

These developments have resulted in the introduction of different forms of organising chronic care. Integrated care (United States of America), shared care (United Kingdom) and 'transmurale zorg' (The Netherlands) are models of organising care that pay heed to the pressure on the quality and costs of chronic care (Van der Linden, 1997). In all these models the kind of relationships between caregivers involved can be characterised. A distinction can be made between complementary relationships and substitution relationships (McGillis Hall, 1997; Scheffler et al., 1996). In complementary relationships the performance of tasks of care is divided between caregivers of different categories in accordance with their level of expertise (McGillis Hall, 1997). When the performance of tasks of care is divided between caregivers by transferring tasks, the relationship is substitution-based (McGillis Hall, 1997; Scheffler et al., 1996). Horizontal substitution refers to the transfer of tasks between caregivers within one level of expertise. Tasks can be transferred from specialist to generalist or from inside the hospital to outside the hospital. The transfer of tasks between caregivers of different levels of expertise is referred to as vertical substitution (Spreeuwenberg, 1994).

In the search for the most effective and efficient combination of health professionals to deliver care for chronic patients, the role of specialised nurses has become important. Specialised nurses perform tasks that traditionally belonged to the domain of the physician, and work inside the hospital – specialised care – as well as outside – general care. In their review of the literature, Scheffler et al. (1996) expect a major contribution of substitution models of care in terms of productivity. They also mention 'the challenges in measuring variations in patient outcomes associated with specific output measures.'

We looked at models of care for chronic patients where the nurse has a central role in order to answer two questions: (1) which outcomes are identified in publications about the effectiveness and efficiency of these models, and (2) are these models of care effective and efficient? After searching for publications about these models in the literature, we compared the models on their main features. We selected the identified or expected effects as well as the statistically significant effects on quality of care, then related these to each other and related the significant effects to the main features of the models. Our interest was generated by the start of a pilot project in Maastricht (The Netherlands) in which the specialised nurse has a central role in the care for patients with diabetes type 2 or chronic obstructive pulmonary disease (COPD).

METHODS

A search of Medline Express was made for studies published between 1966 and January 1999, although a review of only published sources may be subject to bias (Dickersin, 1990). Medline Express contains all citations published in Index Medicus and also corresponds in great part to the International Nursing index. 'Nurse' was entered as keyword and combined with 'effect,' 'outcome(s)' and 'effectiveness.' Studies had to meet four criteria. First they had to be published in English or Dutch or have an abstract in these languages. Second, the design had to be a clinical trial or a randomised clinical trial. Third, patients were restricted to those with diabetes type 2 or COPD and they had to be adults. Finally, the intervention had to deal with nursing care as its main aspect.

The comparability of care models was assessed by looking at several characteristics: type and number of patients, type of care, main caregiver, tasks of the main caregiver, frequency of planned contact with patients, period of intervention and context or country in which the intervention took place. Four tasks of the main caregiver we distinguished based on the intervention planned in Maastricht: direct patient care, organisation and co-ordination of care for individual patients, consultation, and promotion of expertise. Direct patient care includes: anamnesis, physical examination, laboratory requests, giving information and the administration of findings from these activities. Organisation and co-ordination of care refer to activities concerning the continuity of care between caregivers. Consultation refers to those consults given to caregivers or patients in the case of complex situations. Promotion of expertise is about teaching other caregivers or patients and one's own education. If one or more of these activities were mentioned, we assumed the presence of the task.

The publications we examined for expected outcomes and statistically significant differences in outcomes between the experimental and the control group. Expected and significant outcomes were related to each other and to the characteristics of the models. Finally conclusions were formulated with regard to effects on the quality of care of models for chronically ill where the nurse fulfils a central role.

RESULTS

Selected publications

Entering the keywords and using the criteria yielded ten publications (Aubert et al., 1998; Beck et al., 1997; Blake et al., 1990; Brewin & Hughes, 1995; Cockroft et al., 1987; Estey et al., 1990; Kirkman et al., 1994; Littlejohns et al., 1991; Mulloy et al., 1996; Weinberger et al., 1996). Of these studies eight included patients with one

specific disease (Aubert et al., 1998; Blake et al., 1990; Brewin & Hughes, 1995; Cockroft et al., 1987; Estey et al., 1990; Kirkman et al., 1994; Littlejohns et al., 1991; Mulloy et al., 1996) while two studies included patients with different diseases (Beck et al., 1997; Weinberger et al., 1996) (Table 1). The biggest numbers of respondents were reported in the studies with different diagnoses. Response rates in these studies were lowest and did not reach 50%.

Organisation of care

All interventions consisted of a nurse as the main caregiver in the experimental group (Table 1). Interventions were compared with 'usual care' in the control group which consisted of education in one study (Estey et al., 1990), of primary care in two studies (Aubert et al., 1998; Kirkman et al., 1994) of outpatient care in six studies (Beck et al., 1997; Blake et al., 1990; Estey et al., 1990; Littlejohns et al., 1991; Mulloy et al., 1996; Weinberger et al., 1996), of inpatient care in one study (Brewin & Hughes, 1995) and of a combination of inpatient and outpatient care in one study (Cockroft et al., 1987).

In three studies (Aubert et al., 1998; Littlejohns et al., 1991; Weinberger et al., 1996) we identified the performance of three or four tasks by the main caregiver to patients of the experimental group (Table 2). The effects of an intervention with a single task – promotion of expertise – were evaluated in four studies (Blake et al., 1990; Brewin & Hughes, 1995; Cockroft et al., 1987; Mulloy et al., 1996). In the remaining three studies promotion of expertise was accompanied by consultation (once) (Estey et al., 1990) or organisation and co-ordination (twice) (Beck et al., 1997; Kirkman et al., 1994).

Promotion of the expertise of patients was present in all studies. Organisation and co-ordination of care was executed by the nurse in five studies (Aubert et al., 1998; Beck et al., 1997; Kirkman et al., 1994; Littlejohns et al. 1991; Weinberger et al., 1996). Consultation and direct patient care came less frequently under the work of the nurse. Direct patient care was mentioned in two studies and in both of studies was accompanied by the tasks organisation and co-ordination and promotion of expertise (Aubert et al., 1998; Littlejohns et al., 1991).

The studies identified took place in different countries: the United States of America five (Aubert et al., 1998; Beck et al., 1997; Blake et al., 1990; Kirkman et al., 1994; Weinberger et al., 1996), Great Britain three (Brewin & Hughes, 1995; Cockroft et al., 1987; Littlejohns et al., 1991), and Canada and Ireland one each (Estey et al., 1990; Mulloy et al., 1996). In the studies in Canada and in the United States (except one (Blake et al., 1990)) nurses fulfilled two or more tasks, while in studies in Ireland or Great Britain nurses mostly fulfilled just one task: promotion of expertise.

Table 1
Main characteristics of studies

First author	Diagnosis	Number of patients		Type of care		Central care giver experimental
		control	experimental	control	experimental	
Cockcroft (1987)	a	33	42	usual care by general physician and/or hospital doctor	as control plus visits by respiratory nurse	respiratory nurse
Blake (1990)	a	49	45	usual outpatient care	as control plus stress management plan	respiratory nurse
Estey (1990)	b	30	30	3-day educational program and review session	as control plus phone calls and home visit by nurse	registered nurse
Littlejohns(1991)	a	79	73	usual outpatient care	as control plus care by respiratory health worker	nurse specialist
Kirkman (1994)	b	71	204	usual primary care	as control plus phone calls by nurse	diabetes nurse
Brewin (1995)	a	33	12	usual inpatient care	education by respiratory nurse in hospital	respiratory nurse
Weinberger (1996)	c	918	920	customary discharge care	close follow-up by nurse and primary care physician	primary care nurse
Mulloy (1996)	a	30	30	usual outpatient care	education by respiratory nurse in outpatient setting	respiratory nurse
Beck (1997)	d	161	160	usual outpatient care	group outpatient visit care by interdisciplinary team	nurse
Aubert (1998)	a	67	71	usual primary care	nurse case management	nurse

Diagnosis: (a) chronic lung disease, (b) diabetes mellitus, (c) chronic lung disease, diabetes mellitus, congestive heart failure, (d) heart, lung, joint disease, diabetes mellitus

Table 2
Main characters of interventions

First author	Presence of tasks of central care giver #				Frequency of planned contact during intervention	Intervention period (months)	Country
	Direct patient care	Organisation co-ordination	Consultation	Promotion of expertness			
Cockcroft (1987)	0	0	0	1	10	10	Great Britain
Blake (1990)	0	0	0	1	1–3	12	USA
Estey (1990)	0	0	1	1	5	3	Canada
Littlejohns (1991)	1	1	0	1	12	12	Great Britain
Kirkman (1994)	0	1	0	1	12	12	USA
Brewin (1995)	0	0	0	1	1	12	Great Britain
Weinberger (1996)	0	1	1	1	3	6	USA
Mulloy (1996)	0	0	0	1	3	12	Ireland
Beck (1997)	0	1	0	1	12	12	USA
Aubert (1998)	1	1	1	1	26–52	12	USA

Present (1); not present (0)

Twelve months seemed to be the most common length of intervention (seven studies) (Aubert et al., 1998; Beck et al., 1997; Blake et al. 1990; Brewin & Hughes, 1995; Kirkman et al., 1994; Littlejohns et al., 1991; Mulloy et al., 1996). The frequency of planned contacts between the main caregiver and patients ranged from weekly to yearly. In six studies the planned visit was once or twice monthly (Beck et al., 1997; Cockroft et al., 1987; Estey et al., 1990; Littlejohns et al., 1991; Kirkman et al., 1994; Weinberger et al., 1996).

Effects on quality of care

In the selected studies, effects in one or more of the following outcomes were expected: survival, clinical parameters (for example: forced expiratory volume, glycosylated haemoglobin), quality of life, self-care and knowledge, patient satisfaction, medical consumption. Medical records were used to assess survival and medical consumption. Clinical parameters were measured in standardised ways and documented in reports as well. To assess quality of life, self-care, and patient satisfaction questionnaires or interviews were used. Quality of life is in all studies measured with validated instruments. To assess self-care and patient satisfaction not always use is made of validated instruments. Self-care is assessed in different ways depending on the activities involved. Patient satisfaction is measured with self designed instruments in two studies (Kirkman et al., 1994; Weinberger et al., 1996). In all studies statistically significant effects were found in at least one outcome (Table 3).

Improvement in self-care and quality of life were found most often (in four (Brewin et al., 1995; Cockroft et al, 1987; Estey et al., 1990; Mulloy et al., 1996) and three studies (Aubert et al., 1998; Blake et al, 1990; Estey et al., 1990) respectively). Lower costs were reported once (Beck et al., 1997), and improvements in survival (Cockroft et al., 1987; Littlejohns et al., 1991), clinical parameters (Aubert et al., 1998; Brewin & Hughes, 1995) and patient satisfaction (Beck et al., 1997; Weinberger et al. 1996) were found twice. In four studies patients who received care from a nurse showed higher medical consumption than patients who received usual care (Beck et al. 1997; Cockroft et al., 1987; Littlejohns et al, 1991; Weinberger et al., 1996). Less medical consumption when cared for by a nurse was reported twice (Beck et al., 1997; Kirkman et al., 1994). In one study patients cared for by a nurse were found to consume less of some services and more of other services, while costs of care had decreased (Beck et al., 1997).

In all studies at least one identified outcome was evaluated in which no significant difference was found. In seven studies effects in clinical parameters were expected (Aubert et al., 1998; Brewin & Hughes, 1995; Cockroft et al., 1987; Estey et al., 1990; Littlejohns et al., 1991; Kirkman et al., 1994; Mulloy et al., 1996) while these were reported only twice (Aubert et al., 1998; Kirkman et al., 1994). Effects were found in

Table 3
Expected and statistically significant outcomes

First author	Survival	Clinical outcomes	Quality of life	Self-care/ knowledge	Patient satisfaction	Medical consumption		Costs	
						increase	decrease	increase	decrease
Cockcroft (1987)	**	x	x	**		**			
Blake (1990)			**				x		
Estey (1990)		x		**					
Littlejohns (1991)	*	x	**		x	*			
Kirkman (1994)		**		x	x		*		
Brewin (1995)		x		**		x			
Weinberger (1996)			x		**	**			
Mulloy (1996)		x		**					
Beck (1997)			x		**	**	**		*
Aubert (1998)		**	**				x		

(*) not expected and statistically significant outcome; (**) expected and statistically significant outcome; (x) expected outcome and statistically not significant

survival (once (Littlejohn et al., 1991)), medical consumption (twice (Littlejohns et al., 1991; Kirkman et al., 1994)) and costs (once (Beck et al., 1997)) while these had not been mentioned beforehand.

Promotion of the expertise of patients comes under the work of the nurse in all ten studies. When this is the only task of the nurse, in three (Brewin & Hughes, 1995; Cockroft et al., 1987; Mulloy et al., 1996) out of four studies improvement is found in self-care and in two of the studies only in self-care (Brewin & Hughes, 1995; Mulloy et al., 1996).

When organisation and co-ordination is also a task of the nurse, in four out of five studies effects in medical consumption were reported: twice a decrease (Beck et al., 1997; Kirkman et al., 1994) and three times an increase (Beck et al., 1997; Littlejohns et al., 1991; Weinberger et al., 1996). When direct patient care is also the task of the nurse, patients seem to perceive a higher quality of life (Aubert et al., 1998; Littlejohns et al., 1991). Survival, clinical parameters, patient satisfaction and costs show no relation with the presence of task(s) in the selected studies. The number of effects is smaller or equal to the number of tasks performed in eight publications (Aubert et al., 1998; Blake et al., 1990; Brewin & Hughes, 1995; Estey et al., 1990; Kirkman et al., 1994; Littlejohns et al., 1991; Mulloy et al., 1996; Weinberger et al., 1996).

In studies performed in the United States no improvements in self-care were found. Where no relation was found with the presence of tasks, effects on survival were only found in two studies performed in Great Britain (Cockroft et al., 1987; Littlejohns et al., 1991), and effects in clinical parameters (Aubert et al., 1998; Kirkman et al., 1994) and patient satisfaction (Beck et al., 1997; Weinberger et al., 1996) only in two studies performed in the United States. No relation seems to exist between the length of the intervention or the frequency of planned contacts and the number of significant effects found. Only in the studies where patients with different diagnoses were included and with the biggest number of patients were effects found in patient satisfaction (Beck et al., 1997; Weinberger et al., 1996).

DISCUSSION

What outcomes are expected in evaluations of health care models for the chronically ill in which the nurse has a central role? Are these models effective and efficient in terms of patient outcomes? Our search for published studies in Medline revealed little evidence to answer these questions: only ten publications met our criteria. This is not surprising, considering the rather young status of the role of the specialised nurse. It is questionable, therefore, whether more publications would be identified by using alternative keywords or sources in a domain of health care organisation where different approaches have been implemented only very recently. Lengacher et al. (1997)

confirms this: 'the use of outcome measures of nursing practice is not new; however, testing the effects of new delivery models through outcome research is very limited.' In addition McGillis (1997) mentions 'the lack of evaluation of existing (staffing) models while new models emerge rapidly.'

The difficulty of establishing the effectiveness of complex interventions is another possible explanation for the modest number of publications found. All selected publications note the several methodological limitations when the randomised clinical trial is used as research design. Notwithstanding, the randomised controlled trial is the optimal design to tackle the issue of causal inference (Oakley, 1998). Expending the criterion of design to the pretest-posttest design would probably result in a larger number of publications, but would not gain equally valid evidence. Under these circumstances the performance of a meta-analysis will hardly be possible.

We searched in Medline for studies investigating the effects on the quality of chronic care when this care is organised in models where the nurse has a central role. The content of this role differs. In four care models the nurse performs one task: promotion of expertise. In another three care models the nurse performs one other task as well (organisation and co-ordination or consultation). Direct patient care is the task of nurses who perform at least two other tasks as well. Models with multiple tasks for the main caregiver seem to be more prevalent in the United States and Canada than in Great Britain or Ireland. Because the traditional role of nurses is different from one country to another, as is their position in health hierarchy (Stallknecht, 1992), differences in models and in the role of the nurse herein exist between countries. In spite of the degree of centrality, organising chronic care to meet the needs of patients by placing the nurse in a more central role, means a shift in primary attention from pathology to the person with the chronic disease (Taylor, 1995). Together with more room for the interpersonal and moral competencies of nurses, more attention is paid to the interactive process of patient education and counseling.

The targets of care define an intervention and the content of an intervention defines which effects can be expected. All selected publications deal with chronic care in which the nurse has a central role. Therefore all interventions included try to meet the targets of care for chronic patients in general and for patients with DM or COPD specifically. We classified the outcomes mentioned in the selected studies according to the distinctions of patient outcomes made by Donabedian (1992), Long et al. (1993) and Driessen et al. (1994). They seem to agree on which patient outcomes have to be evaluated when the goal is to assess the effects of an intervention on the quality of care. Medical consumption and costs of care are related to the aspect of efficiency, while all other outcomes – survival, clinical parameters, quality of life, self-care and patient satisfaction – are seen as indicators for the aspect of effectiveness.

One important limitation of the literature reviewed is that not always use is made of validated measures to assess the effects on quality of care. Data about survival,

medical consumption and clinical parameters are obtained from medical records of which the content validity is often poor especially when they are hand written. For the assessment of patient satisfaction in two studies use is made of self designed instruments of which nothing is mentioned about the reliability and reliability.

Depending on the task(s) performed by the nurse, significant effects were reported. Promotion of expertise seems to improve self-care. When the nurse organises and co-ordinates care, it has an effect on medical consumption. Direct patient care performed by the nurse seems to improve the quality of life perceived by patients. In eight of the publications the number of effects is smaller or equal to the number of tasks performed by the nurse.

The results of this review allow us to draw the following conclusions. First of all the domain of effect evaluation of models of chronic care where nurses have a central role is young. Together with the difficulties of using the randomised clinical trial as research design for these health care models, our search in Medline yielded only a modest number of publications. Comparing the selected publications showed effects on the quality of care for chronic patients. The type of effect that can be expected seems to depend on the content of the intervention. Interventions for patients with DM or COPD in which the nurse fulfils a central role do not seem to affect clinical parameters as often as is expected. However, one could ask if it is realistic to expect changes in clinical parameters within the modal research period of one year. More likely, these interventions would improve self-care and quality of life. Higher patient satisfaction and more medical consumption by patients who received care in these models are effects one can have reasonable confidence in. These effects were found in larger studies although not always use was made of validated measures. Higher costs of care or higher medical consumption may be necessary to achieve 'tailor-made' care and may therefore not be undesirable.

More, methodologically suitable and valid evaluations of the effects and the process of chronic care are needed to provide knowledge about how to structure chronic care in a way to achieve 'high-quality' care.

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4 CHAPTER

Substitution model with central role for nurse specialist is justified in the care for stable type 2 diabetic outpatients

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ABSTRACT

Aim of the study. Assessment of effects on quality of care, in terms of patient outcomes, when tasks in the care for outpatients with stable type 2 diabetes are transferred from internist to nurse specialist and from outpatient clinic to general practice.
Background. For the management of chronic diseases with a high prevalence and requiring current monitoring, it is suggested that substitution of care may be an appropriate solution to safeguard high quality care.
Design & Methods. A 12-month non-equivalent control group design was used. General practitioners (GPs) referring diabetes patients to the university hospital Maastricht were asked to choose for the traditional model or the nurse specialist model. Informed consent was obtained from patients with stable diabetes type 2 attending these practices. All patients received care according to the model chosen by their GP. Identified outcomes were: clinical status, health status, self-care behaviour, knowledge of diabetes, patient satisfaction, and consultation with care-providers.
Results. In the control group no patients were treated with oral hupoglycaemic agents (OHA) only. The control group was compared with an intervention subgroup (n=52) also without patients receiving OHA only. Clinical data were available for all patients. Patients without complete data from questionnaires had better mean concentration of HbA_{1c} than patients with complete data (p=0.004). The traditional care model and the nurse specialist model achieved equal outcomes, while glycaemic control of patients in the nurse specialist model improved (from 8.6% to 8.3%) but deteriorated in the traditional model (from 8.6% to 8.8%; p-value between groups = 0.001).
Conclusions. The model with nurse specialists taking on roles and tasks beyond those traditionally regarded as their remit as well as new ones, is effective for the care of stable diabetic outpatients.

INTRODUCTION

The world's diabetic population will probably have doubled from an estimated 135 million now to 300 million in 2025 (WHO, 1997). As a result all European countries, the International Diabetes Federation and the World Health Organisation have declared a commitment to maximising the management of care for patients with diabetes mellitus (WHO/IDFE, 1990). As in other Western countries, the Netherlands is faced with a growing number of people with diabetes in combination with a limited capacity of health care resources. The latter are also being stretched by a policy of cost control. One of the challenges for the health care system is to provide this growing diabetic population with high quality care that is cost-effective, widely available and easily accessible.

At the moment, patients with type 2 diabetes in the Netherlands receive care from a general practitioner (GP) or an internist (a medical specialist in internal medicine). More than 90% of consultations given by both sets of care-providers are repeat consultations (Mooy & Vondeling, 1996). For the management of chronic diseases with a high prevalence and many recurring checks, it is suggested that substitution of care may be an appropriate solution.

Substitution of care can be divided into horizontal and vertical substitution. Horizontal substitution refers to the transfer of tasks between care-providers within one level of expertise. This means that tasks can be transferred from specialist to generalist or from inside to outside the hospital. Vertical substitution refers to the transfer of tasks between care-providers with different levels of expertise. Substitution does not automatically imply a complete transfer, but it can also mean that professionals share tasks and responsibilities to remove deficiencies in care (Spreeuwenberg, 1994).

For outpatients with stable type 2 diabetes, who are now treated by an internist, an alternative treatment programme was proposed. This alternative includes both forms of substitution: a transfer of tasks to the nurse specialist as well as to the general practice. The involvement of the nurse specialist in the care of patients with a chronic disease can be justified on the basis of several arguments. Training programmes for nurses focus more on the behavioural and preventive aspects of health care than training programmes for physicians. Nursing skills are increasingly in demand in an environment, like diabetes care, that is moving more towards outpatient care and that requires its health care-providers to function as teams and to assume managerial responsibilities (IFTF, 2000).

The effectiveness of the nurse specialist in the care of chronically ill patients can be well evaluated in terms of the structure-process-outcome model (Donabedian, 1980). Evaluation studies regarding process and/or outcome variables are limited, mainly due to the -as yet- underdeveloped nature of this field of study (McGillis Hall, 1997; Lengacher et al., 1997; Temmink et al., 2000; Vrijhoef et al., 2000). The research issue addressed here concerns effects on outcomes of a change in the structure of care for 'stable' type 2 diabetic patients receiving care from an internist in an outpatient department of a hospital. For this, a quasi-experimental design was used to compare the substitution model with the traditional model in terms of patient outcomes. The substitution model can only be justified if the quality of generated care is at least equivalent to the quality of outpatient diabetes care performed by the internist.

METHODS

Study design and patients

Effects on outcome were measured in a non-equivalent control-group design (Cook & Campbell, 1979). In the Maastricht region about 82 GPs refer patients with type 2 diabetes to the university hospital Maastricht. These GPs were asked to choose between three models of diabetic care for those patients currently referred to the internist. These models are:

- the traditional model of outpatient care, in which patients receive quarterly consultations from the internist in the hospital as well as education and self-management skills by the nurse specialist in the hospital;
- a new model in which the GP and the medical specialist jointly consult patients in general practice (being evaluated at the moment);
- a new model in which the nurse specialist plays the central role as described below *(see: Intervention)*.

Twenty-nine GPs opted to continue with the traditional outpatient model, while 22 GPs opted for the nurse specialist model. From the participating 22 GPs a survey of patients with type 2 diabetes receiving outpatient care was compiled by the hospital. The internists were asked to assess which diabetes patients could be assumed to have 'stable' diabetes as defined by a set of criteria (Figure 1). This assessment took place in two phases, firstly by looking at medical records and, secondly, by examining patients.

When patients were assessed as being eligible, they received information about the substitution model from their internist and written informed consent was requested. For the patients receiving traditional outpatient care the same procedure to assess stability and receive informed consent was followed. Clinical data were collected on commencement and at each subsequent consultation within one year. Data on other aspects of quality of care were collected by questionnaire on commencement of the study (T0), and after six (T6) and 12 months (T12). To facilitate response, questionnaires could be returned in pre-paid envelopes, assistance was offered in a covering letter and, if necessary written reminders were sent two and four weeks after the questionnaire had been sent out. The study was approved by the ethics committee of the university hospital Maastricht.

Intervention

The nurse specialist model is designed for those patients with stable type 2 diabetes who receive outpatient care from the internist. In the substitution model, patients receive three quarterly consultations from a nurse specialist in general practice. Annually, patients receive an extensive check-up by the internist in the hospital. The

Figure 1
'Stability' criteria

Inclusion criteria:

- diagnosed with non-insulin dependent diabetes mellitus (World Health Organisation criteria);
- a concentration of glycated haemoglobin (HbA_{1c}) <10.5% for the preceding 6 months at least. Measurement of HbA_{1c} has to take place at three different and successive moments in time. The most recent concentration has to be within the range of 1%-point of the mean for all three measurements.

Exclusion criteria:

- presence of active complications (micro and macro-angiopathy);
- presence of other diseases not related to diabetes mellitus for which care of a medical specialist is received;
- presence of psychosocial problems (assessed by physician).

nurse specialist is a registered nurse with the highest level of qualification and specialised in a disease. Nurses involved in this study are specialised in diabetes and have long-term work experience.

The care is based on a protocol developed by all parties involved in the care of patients with type 2 diabetes. In this protocol the tasks of each provider are clearly defined. Tasks (activities) of the nurse specialist are concerned with direct patient care (medical history taking, physical examination, interpretation of laboratory tests, administration and assimilation of findings), organisation and co-ordination of care for individual patients (identification of shortcomings in care, referral to and communication with care-providers), consultation (providing advice to patients and other care-providers), and advancement of expertise (education of patients, themselves and other care-providers). If complications or other problems arise, the nurse will consult the GP or the internist. During office hours the nurse specialist is the first care-provider to contact.

Once a year the internist performs a complete check-up. If necessary he draws the nurse's attention to particular aspects of care. The GP provides the nurse with a working place in the practice. Every consultation performed by the nurse is briefly discussed with the GP. Outside office hours the GP is the first care-provider to contact.

Outcome measures

For the purpose of this study, indicators were selected which are considered to be essential when looking at outcomes in quality of care research for chronically ill (Donabedian, 1992; Long et al., 1993; Driessen et al., 1994). These are:

- Clinical status was determined by glycated haemoglobin concentration (HbA_{1c}), levels of fasting total cholesterol, HDL-cholesterol and triglycerides, body mass

index (BMI), systolic (SBP) and diastolic blood pressure (DBP). Measurement of lipid levels, weight and blood pressures occurred annually, while HbA_{1c} concentration was measured quarterly.

- Health status was measured using the Dutch version of the COOP/WONCA charts and a visual analogue scale (VAS) (Maxwell, 1978; Nelson et al., 1987; Van Weel, 1993). The charts consist of six single-item measures: physical fitness, feelings, daily activities, social activities, change in health and overall health. Each chart represents a distinct domain, refers to fortnightly period, and has a five-point Likert scale where five designates the worst level. These charts have been extensively used in chronic diseases, have proven acceptability by patients as well as satisfactory clinical validity (Nelson et al., 1987; Van Weel, 1993). The visual analogue scale was used as single-item measure of quality of life. It consists of a 10 centimetre long horizontal line with 'low quality of life' at its left-hand extremity and 'high quality of life' at its right-hand extremity. It is simple to use, largely acceptable and regarded as a valid and reliable instrument to measure quality of life (Maxwell, 1978). For both instruments Dutch versions were used.
- Self-care behaviour was measured with a Dutch disease specific instrument, the Self-Care Behaviour Check-list (SCBC) which consists of four factors: self-regulation (3 items), bodily observation and conditioning (3 items), recording activity of condition (4 items), and diet application and commitment (8 items) (Pennings-van der Eerden, 1992). Every item is measured with a five-point Likert scale ranging from 'never' to 'always.' Scores for each factor were computed by summing the valid answers and dividing this sum by their number (range 1–5). The total score of self-care was achieved by adding together the scores of all answered items and dividing it by their number (range 1–5). The SCBC was found to be a valid instrument to measure self-care amongst diabetes patients (Pennings-van der Eerden, 1992).
- For the measurement of disease specific knowledge of patient, use was made of a Dutch diabetes specific instrument containing 12 multiple choice questions (Ripken et al., 1990). Each correct answer yields one point. The total score was achieved by adding together the correct answers (range 0–12). No information about the reliability of the instrument used was found and thus evidence was gathered during this study.
- Patient satisfaction about received diabetic care was measured by asking patients to grade their satisfaction with a score (between 1 for 'low quality of care' and 10 for 'high quality of care'), if they would recommend the care they had received to other patients ('yes' or 'no') and if they intended to continue making use of this care in the future ('yes,' 'no,' 'no preference'). These items are derived from industrial marketing management and have been applied earlier in the same area of research (Cockroft et al., 1987; GRASSIC, 1994).

- The number of consultations of patients for their diabetes was derived by asking patients about the number of consultations received from nurse specialist, GP, and/or internist.

Data on clinical parameters were derived from the clinical notes taken by the nurse and/or internist. Data on all other outcomes were obtained directly from patients by questionnaires.

Statistical analysis

Differences between intervention group and control group and between patients with complete data and patients with missing data were tested, using chi-square test and Student's t-test for independent samples. The distribution of patients with missing data and of deceased patients were tested with chi-square test.

To assess differences in HbA_{1c} within and between groups, one factor repeated-measures analysis of variance was used. Correlation between change in HbA_{1c} and change in the units insulin prescribed, change in dose OHA prescribed, or change in self-care behaviour were tested with Pearson correlation. 'Change' was obtained by subtracting the final value from the original value. Comparison of groups for lipids, BMI and blood pressures was performed with Student's t-test for independent samples, while within group comparisons were performed with Student's t-test for paired samples.

One factor repeated measures analysis was used to compare measurements within groups and between groups for COOP/WONCA charts, VAS for quality of life, self-regulation, knowledge, and satisfaction score. Recommendation of care and future use were described in percentages. Comparisons of the number of consultations with main care-providers within groups was performed with Friedman test, while Kruskal-Wallis one-way analysis of variance was used for between group comparisons.

All data were analysed on the basis of intention to treat: patients who did not adhere to the management plan in which they initially participated, were still assumed to have done so for the purpose of analysis. A significance level, $p=0.05$ (two tailed) was used. Data processing and analyses were conducted with SPSS (Windows Release 8.0).

RESULTS

Patients

Of the 22 participating GPs, 237 outpatients with type 2 diabetes were available of whom 105 patients had stable diabetes. Of these 105 patients, 74 patients gave

informed consent (intervention group). Of the 29 GPs who continued to use the traditional model, 105 outpatients with type 2 diabetes were available, of whom 60 patients had stable diabetes. Of these 60 patients, 47 gave informed consent (control group).

Reasons for not giving informed consent in the control group were: too much difficulty (1 patient), too old (2), no interest (4), and unknown (6). In the intervention group: no interest (1), moving house (1), preference for internist as care-provider (18), and unknown (11). Depending on the model chosen by their GP, patients who did not gave informed consent received care according to traditional model or the nurse specialist model.

Comparison of patients in the intervention group with the control group on relevant baseline characteristics showed fairly comparable groups except for diabetes therapy (Table 1). Without patients in the control group being treated with oral hypoglycaemic agents (OHA) only, further analyses were performed between patients receiving similar treatment, i.e. OHA and/ or insulin. The part of the intervention group treated with OHA and/ or insulin (n=52) - hereinafter referred to as intervention subgroup - was comparable on baseline characteristics with the control group (Table 1).

Not all patients completed the study. Data from all questionnaires were available for 54 patients. The distribution of patients in the intervention subgroup and in the control group for whom data were complete (59.6% and 48.9% respectively) and incomplete, did not differ significantly. For patients for whom incomplete data were available only clinical data were obtainable. Comparison of groups with and without complete data on baseline characteristics revealed that groups were similar except for HbA_{1c}. Mean concentration of HbA_{1c} was 0.7% lower for patients without complete data (7.8±1.2% versus 8.6±1.3%; p=0.004). Main reasons for non-response were a lack of interest in returning the questionnaire(s) and death. Of the patients in the intervention subgroup three died during the study, while two patients in the control group died (χ^2=0.118, p=0.731). In all cases, the cause of death was not directly related to diabetes.

Outcomes

The findings from baseline comparisons led to an assessment of the outcomes between patients for whom complete data were available for the intervention subgroup and for the control group. For clinical parameters analyses were also performed without the restriction of complete data.

Changes in mean HbA_{1c} levels are shown in table 2. The first two means of HbA_{1c} level in the intervention subgroup were derived when the central care role was performed by the internist, while last three means were derived when the nurse performed the central role.

Table 1
Baseline comparisons for patients in the intervention group, intervention *sub*group and the control group

Patient characteristics[a]	Intervention group (n=74)	Intervention *sub*group (n=52)	Control group (n=47)	p-value[b]	p-value[c]
Age (years)	66.4 ± 10.7	68.2 ± 9.7	66.4 ± 9.3	0.973[d]	0.354[d]
% (No) male sex	43.2 (32)	63.5	51.1 (24)	0.400[e]	0.213[e]
Duration of diabetes (years)	10.9 ± 6.5 [67]	12.6 ± 6.2 [48]	12.6 ± 9.1	0.241[d]	0.996[d]
% (No) therapy					
oral hypoglycaemic agents	26.8 (19)		-		
oral hypoglycaemic agents and insulin	11.3 (8)	15.4 (8)	25.5 (12)		
insulin	62.0 (44) [71]	84.6 (44)	74.5 (35)	0.000[e]	0.209[e]
HbA_{1c} (%)	7.9 ± 1.6	8.3 ± 1.5	8.2 ± 1.1 [46]	0.171[d]	0.898[d]
Total cholesterol (mmol/l)	5.6 ± 1.1 [69]	5.7 ± 1.1 [51]	5.6 ± 1.3 [35]	0.811[d]	0.706[d]
HDL-cholesterol (mmol/l)	1.1 ± 0.3 [67]	1.1 ± 0.3 [49]	1.1 ± 0.3 [27]	0.567[d]	0.681[d]
Triglycerides (mmol/l)	1.9 ± 1.2 [67]	2.0 ± 1.3 [49]	2.1 ± 1.3 [27]	0.533[d]	0.769[d]
Body mass index (kg/m^2)	28.5 ± 5.7 [58]	29.7 ± 4.3 [41]	31.0 ± 6.2 [28]	0.068[d]	0.311[d]
Systolic blood pressure (mmHg)	143.1 ± 12.9 [66]	143.2 ± 13.4 [47]	143.6 ± 18.2 [41]	0.874[d]	0.917[d]
Diastolic blood pressure (mmHg)	81.2 ± 8.7 [66]	80.7 ± 9.5 [47]	80.4 ± 10.1 [41]	0.688[d]	0.884[d]
% diabetic complications					
neuropathy	47 [68]	52 [48]	49	0.843[e]	0.759[e]
nephropathy	53 [68]	58 [48]	40	0.187[e]	0.081[e]
coronary heart disease	41 [68]	44 [48]	57	0.086[e]	0.182[e]
peripheral vascular disease	16 [69]	20 [49]	11	0.416[e]	0.188[e]
retinopathy	36 [66]	43 [47]	45	0.373[e]	0.835[e]

[number of patients for which data are used in case data were not available for all patients]; [a] figures are means ± sd unless stated otherwise; [b] significance level of test between intervention group and control group; [c] significance level of test between intervention *sub*group and control group; [d] t-test; [e] Likelihood-ratio chi square test

Changes between means of HbA_{1c} level in the intervention subgroup were statistically significant, with last three means being smaller than first two. In the control group changes between means of HbA_{1c} were also statistically significant. Between groups the differences in mean HbA_{1c} levels increased towards the end of the study. The

Table 2

Effects on HbA_{1c} concentration for the intervention subgroup treated with OHA and/or insulin and the control group

Group	n	months after start of study (mean ± sd)					within group		between groups	
		0	3	6	9	12	F-statistic	p-value	F-statistic	p-value
Intervention *sub*group	52	8.3 ± 1.5	8.4 ± 1.3	8.1 ± 1.2	7.9 ± 1.0	8.2 ± 1.0	3.776	0.012[a]		
Control	46	8.2 ± 1.1	8.2 ± 1.0	8.4 ± 1.1	8.5 ± 1.3	8.5 ± 1.4	2.744	0.044[a]	5.999	0.000[a]
With complete data:										
Intervention *sub*group	31	8.6 ± 1.4	8.7 ± 1.1	8.3 ± 1.1	8.2 ± 1.0	8.3 ± 1.0	3.396	0.018[a]		
Control	23	8.6 ± 1.1	8.4 ± 1.1	8.9 ± 1.1	8.9 ± 1.1	8.8 ± 1.3	2.243	0.099[a]	5.386	0.001[a]

[a] Greenhouse-Geisser adjusted univariate approach

differences between groups in repeated mean HbA_{1c} levels were statistically significant. When limiting groups to patients with complete data almost the same picture emerged except that the differences between means in the control group were not statistically significant. Between groups the differences in repeated mean HbA_{1c} levels were statistically significant.

Within the intervention subgroup mean total cholesterol declined by 0.5 mmol/l and mean HDL-cholesterol increased by 0.1 mmol/l. Both changes were statistically significant. For triglycerides no differences were seen in the intervention subgroup as was the case for all lipids in the control group. Between groups no differences were found in mean concentration of lipids. Restriction to patients with complete data also showed a decline of 0.5 mmol/l in total cholesterol within the intervention subgroup.

With regard to BMI no statistically significant changes occurred within or between groups. The changes between mean values of SBP in both groups were statistically significant. Mean SBP in the intervention group increased by 3.6 mmHg, while mean SBP in the control group decreased by 3.0 mmHg. Between groups no changes were found in mean SBP. For DBP no changes were seen between or within groups.

With regard to the COOP/WONCA charts fairly, steady mean values were found for all scales in both groups (Table 3). None of the changes within or between groups was found to be statistically significant. On the VAS for quality of life amongst patients, no statistically significant changes were found within or between groups. With means under or around the middle of possible values, the VAS reflected poor quality of life amongst patients.

The improvement in self-regulation by patients in the intervention subgroup was statistically significant (Table 4). Improvement here means more frequent performance. Within the control group or between groups no statistically significant changes were found. Data required to assess overall scores in self-care behaviour -scores on all sub-scales at all measurements- could only be obtained for 18 patients in the intervention subgroup and for 13 patients in the control group. The mean level of knowledge of diabetes of patients was found to be moderate and the changes within or between groups were not statistically significant. The reliability of the knowledge test proved to be satisfactory (α=0.80).

Mean satisfaction marks for patients in both intervention subgroup (7.8±1.4; n=29) and control group (8.1±1.0; n=21) were high. No statistically significant changes were found within or between groups. At baseline, the response of 86% of patients in the intervention subgroup (n=28) was to recommend traditional care to others. After having received care according to the substitution model, the response of 89% patients at both T6 and T12 was to recommend care with a nurse in the central care role. For each of the three measurements in the control group (n=21), 95% recommended using traditional care. When patients were asked if they would make use of care in the future, at T0 96% of patients in the intervention subgroup said they

Table 3
Effects on health status for the intervention *sub*group treated with OHA and/or insulin and the control group

Outcome (min-max)	n	measurement (mean ± sd)			within group		between groups	
(Group)		T0	T6	T12	F-statistic	p-value	F-statistic	p-value
Quality of life: Physical fitness (5–1)								
Intervention *sub*group	31	3.3 ± 1.5	3.1 ± 1.5	3.2 ± 1.4	0.390	0.679		
Control	20	3.2 ± 1.3	3.3 ± 1.4	3.2 ± 1.3	0.110	0.896	0.281	0.720[a]
Quality of life: Feelings (5–1)								
Intervention *sub*group	31	2.3 ± 1.2	2.5 ± 1.1	2.2 ± 1.0	0.498	0.610		
Control	23	2.0 ± 1.2	2.0 ± 1.1	2.3 ± 1.1	1.335	0.272[a]	1.107	0.335
Quality of life: Daily activities (5–1)								
Intervention *sub*group	32	2.4 ± 1.1	2.4 ± 1.2	2.7 ± 1.2	1.239	0.297		
Control	23	2.0 ± 1.1	2.3 ± 1.2	2.2 ± 1.2	0.702	0.501	0.935	0.396
Quality of life: Social activities (5–1)								
Intervention *sub*group	29	2.1 ± 1.3	2.2 ± 1.4	2.0 ± 1.1	0.330	0.721		
Control	23	1.9 ± 1.0	1.9 ± 1.2	2.0 ± 1.2	0.169	0.787[a]	0.391	0.678
Quality of life: Change in health (5–1)								
Intervention *sub*group	30	2.9 ± 0.7	2.9 ± 1.0	2.9 ± 0.9	0.021	0.980		
Control	23	2.9 ± 0.5	2.8 ± 0.8	2.9 ± 1.0	0.117	0.890	0.096	0.908
Quality of life: Overall health (5–1)								
Intervention *sub*group	32	3.4 ± 0.8	3.5 ± 0.9	3.6 ± 0.7	1.130	0.322[a]		
Control	23	3.6 ± 1.0	3.4 ± 0.9	3.3 ± 0.9	0.870	0.391[a]	1.951	0.147
Quality of life: VAS (0–10)								
Intervention *sub*group	30	4.3 ± 2.5	4.3 ± 2.9	4.3 ± 2.8	0.009	0.991		
Control	21	4.2 ± 2.6	5.1 ± 2.2	4.2 ± 2.9	3.076	0.057	1.324	0.271

T0 baseline; T6 first post measurement; T12 second post measurement; [a] Greenhouse-Geisser adjusted univariate approach

Table 4

Effects on self-care and knowledge for the intervention *sub*group treated with OHA and/or insulin and the control group

Outcome (min-max)	n	measurement (mean ± sd)			within group		between groups	
(Group)		T0	T6	T12	F-statistic	p-value	F-statistic	p-value
Self-care behaviour: Diet application (1–5)								
Intervention *sub*group	19	3.2 ± 1.1	3.3 ± 1.0	3.4 ± 1.0	1.332	0.274[a]		
Control	15	3.3 ± 0.7	3.5 ± 1.1	3.3 ± 1.0	0.432	0.593[a]	0.939	0.374[a]
Self-care behaviour: Self-regulation (1–5)								
Intervention *sub*group	30	3.1 ± 1.2	3.2 ± 1.1	3.6 ± 1.1	4.617	0.014		
Control	22	3.9 ± 1.0	4.0 ± 0.9	4.0 ± 1.0	0.256	0.776	1.403	0.251
Self-care behaviour: Activity of condition (1–5)								
Intervention *sub*group	19	3.0 ± 1.3	3.0 ± 1.3	3.0 ± 1.1	0.010	0.990		
Control	16	2.7 ± 1.2	2.7 ± 1.1	3.0 ± 1.2	0.899	0.389[a]	0.418	0.660
Self-care behaviour: Bodily observation and conditioning (1–5)								
Intervention *sub*group	26	3.8 ± 1.0	4.3 ± 0.7	3.9 ± 1.2	3.117	0.053		
Control	22	3.6 ± 1.1	3.9 ± 1.1	3.7 ± 1.3	0.505	0.607	0.320	0.727
Self-care behaviour: Overall (1–5)								
Intervention *sub*group	18	3.2 ± 0.8	3.5 ± 0.6	3.5 ± 0.7	1.526	0.236[a]		
Control	13	3.6 ± 0.6	3.7 ± 0.7	3.5 ± 0.6	0.370	0.694	0.696	0.464[a]
Knowledge (0–12)								
Intervention *sub*group	32	7.7 ± 3.3	7.8 ± 2.7	8.0 ± 3.0	0.451	0.639		
Control	23	8.3 ± 2.7	8.1 ± 2.9	8.7 ± 2.3	1.125	0.334	0.245	0.783

T0 baseline; T6 first post measurement; T12 second post measurement; [a] Greenhouse-Geisser adjusted univariate approach

Table 5
Consultations with patients in the intervention *sub*group and the control group with the care-providers

Outcome (min-max)	n	measurement (mean ± sd)			within group		between groups p-values (Chi-square, p-value)					
(Group)		T0	T6	T12	Chi-square	p-value	T0		T6		T12	
Consultations with nurse specialist												
Intervention *sub*group	31	0.6 ± 1.1	2.5 ± 1.1	2.4 ± 1.4	33.146	0.000						
Control	22	0.8 ± 1.5	0.7 ± 0.9	0.8 ± 1.1	0.333	0.846	0.170	0.680	26.720	0.000	16.919	0.000
Consultations with GP												
Intervention *sub*group	31	0.5 ± 1.3	0.9 ± 1.6	1.0 ± 1.4	1.962	0.375						
Control	22	0.8 ± 1.2	0.6 ± 2.8	1.2 ± 3.4	4.688	0.096	1.286	0.257	3.004	0.083	2.274	0.132
Consultations with internist												
Intervention *sub*group	31	2.1 ± 1.6	0.4 ± 0.9	0.9 ± 0.5	26.248	0.000						
Control	22	1.9 ± 0.8	1.7 ± 0.6	1.9 ± 0.9	0.047	0.977	0.563	0.453	27.231	0.000	18.141	0.000
Consultations with nurse specialist + GP + internist												
Intervention *sub*group	31	3.2 ± 2.1	3.8 ± 2.5	4.3 ± 2.2	4.750	0.093						
Control	22	3.4 ± 2.2	3.0 ± 3.1	3.9 ± 4.0	3.233	0.199	0.051	0.822	2.149	0.143	3.757	0.053

TO baseline; T6 first post measurement; T12 second post measurement

would use traditional care. After having received care with the nurse as central care-provider, both at T6 and T12, 89% of patients said they would make use of the substitution model in the future, while 4% of patients showed no particular preference between traditional care and substitution model. For all measurements the entire control group said that it would make use of traditional care in the future.

Within the intervention group statistically significant changes for consultations of care-providers were found (Table 5). During the study the mean number of consultations with the nurse specialist multiplied by four to 2.4 consultations at T12, while the mean number of consultations with the internist decreased from 2.1 at T0 to 0.9 at T12. Changes in the total number of consultations with care-providers were not statistically significant. Within the control group no statistically significant changes were found in mean number of consultations with individual nor with all care-providers together. The differences between groups in mean number of consultations with the nurse specialist (higher in the intervention group) and mean number of consultations with the internist (higher in the control group), were statistically significant.

DISCUSSION

Can the transfer of (medical) tasks from an internist to a nurse specialist be justified for the care of stable diabetic outpatients? The arguments contained with this evaluation into the effects on quality of care would seem to suggest that this can be answered affirmatively. It was found that the traditional care model and the nurse specialist model achieved equal patient outcomes in terms of lipid spectrum, BMI, BP, quality of life, self-care behaviour, knowledge of diabetes, patient satisfaction, and overall number of consultations with care-providers, while the glycaemic control of patients in the nurse specialist model is somewhat better than for patients receiving traditional care. So, from this study preliminary evidence was obtained, proving that the nurse specialist model may replace the traditional outpatient model effectively.

Several methodological limitations of this study should be acknowledged. The optimal design to tackle the issue of causal inference is the randomised controlled trial (Oakley, 1998). Under less optimal circumstances, quasi-experimental evaluation may be considered to provide evidence or 'proof of effect' (Van Weel & Knottnerus, 1999). The requirements for GPs to participate in this study did not allow random allocation. GPs who participate in the substitution model may have a special interest in innovations with respect to (diabetes) care. To support the credibility of results, comparable groups were analysed. For this patients being treated with OHA only were excluded from the intervention group. Response rates and completion rates were common for longitudinal studies with the chronically ill.

Patients with missing data from questionnaires had better mean glycaemic control. With improved glycaemic control found in both intervention subgroup of patients with complete data as in entire intervention subgroup (with + without complete data), one can have reasonable confidence in this effect. Good glycaemic control can delay onset and slow down progression of diabetic complications for patients with type 2 diabetes (UKPDS, 1998).

The nurse specialist model targets type 2 diabetic outpatients with stable metabolic control. During inclusion of patients the cut-off value for HbA_{1c} was increased with 1.5%-point. This resulted in an expansion of the study population by about 20% with means of HbA_{1c} in both intervention group and control group in the order of the entire outpatient population as assessed before (Wolffenbuttel, 1991). General instruments were used to enable assessment of effects of the substitution model more generally. Together with a research period of one year, this might have resulted in not finding existing effects in outcomes.

A review of the literature showed improvements in self-care, quality of life, patient satisfaction and increased consumption of medical care depending on the way in which tasks were divided between care-providers (Vrijhoef et al., 2000). Improved glycaemic control was found in two trials with the nurse specialist making follow-up telephone calls (Kirkman et al., 1994; Aubert et al., 1998). Expected improvements in knowledge and self-care in this study were not evident. In usual outpatient care the nurse is already involved in the more traditional way.

Two issues need to be addressed in further research. Improved glycaemic control might result from life-style changes and/ or therapy (Fisher et al., 1997). In this study no correlations were found between change in HbA_{1c} and change in dose of medication or change in self-care behaviour. However, stable diabetic patients, already familiar with a nurse specialist, are transposed into restricted ranges of both level of HbA_{1c} and self-care behaviour. Secondly, although substitution of care-providers occurred, no evidence was provided about the model's cost-effectiveness. The quantity of consultations consumed, does not reflect costs.

In conclusion, this evaluation revealed that consistent follow-up care using nurse specialists who follow protocols and who are the primary interface with the patient, is an appropriate solution for managing the care of stable diabetic outpatients. The transfer of (medical) tasks from the internist to the nurse specialist and, simultaneously, from outpatient to primary care in the care for stable type 2 diabetic patients resulted in at least equal outcomes as traditional diabetic outpatient care.

Rather than just adding a new care-provider, more responsive models of care are developed that have the potential to improve the delivery of care and patient outcomes (Vrijhoef et al., 2001). With nurse specialists taking on roles and tasks beyond those traditionally regarded as their remit as well as new ones, more equitable and less hierarchical models of multi-professional team working in the care for chronically ill become

available. For patients with diabetes promising results were found from a model where the nurse specialist plays a central role.

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5 CHAPTER

The nurse specialist as main care-provider for patients with type 2 diabetes in a primary care setting: Effects on patient outcomes

by Vrijhoef HJM, Diederiks JPM, Spreeuwenberg C, Wolffenbuttel BHR, Van Wilderen LJGP.

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ABSTRACT

A solution to safeguard high quality diabetes care may be to allocate care to the nurse specialist. By using a one group pretest-posttest design with additional comparisons, this study evaluated effects on patient outcomes of a shared care model with the diabetes nurse as main care-provider for patients with type 2 diabetes in a primary care setting. The shared care model resulted in improved glycaemic control, additional consultations and other outcomes being equivalent to diabetes care before introduction, with the general practitioner as main care-provider. Assignment of care for patients with type 2 diabetes to nurse specialists seems to be justified.

INTRODUCTION

As health care delivery is being reconfigured, so is the future role of care-providers. Diabetes care has gradually moved from the more traditional hospital clinic to care shared between secondary and primary care-providers (Hampson et al., 1996). However, because most patients with type 2 diabetes are being treated in primary care (De Sonnaville, 1997), because there is an increasing prevalence rate (Ruwaard et al., 1993), and because general practitioners (GPs) are facing a heavy and increasing workload (Van Duijn and Mentink, 1998), a solution to safeguard high-quality diabetes care in the Netherlands may be to transfer the work carried out by physicians to other health care professionals.

Substitution of care can be divided into horizontal and vertical substitution. Horizontal substitution refers to the transfer of tasks between care-providers with comparable levels of expertise. This means that tasks can be transferred from specialist to generalist or from inside the hospital to outside the hospital. Vertical substitution refers to the transfer of tasks between care-providers across different levels of expertise. Substitution does not automatically imply a complete transfer, but it can also mean that professionals share tasks and responsibilities to bridge deficiencies in care (Spreeuwenberg, 1994).

Following the US and the UK, the Netherlands too have seen nurses in a particular area of care expand their specialist skills into areas perhaps more traditionally seen as the activity of medicine (Barton et al., 1999). Despite the popularity of nurse specialists performing a new role in chronic care that challenges established professional boundaries, evaluation studies regarding outcome and/or process variables are limited mainly due to the -as yet- underdeveloped nature of this field of study (McGillis Hall, 1997; Lengacher et al., 1997; Temmink et al., 2000; Vrijhoef et al., 2000).

In five general practices (11 GPs) in the region of Venlo a pilot project was introduced in which a diabetes nurse performs the role as main care-provider within a

shared care model for patients with type 2 diabetes. The jointly formulated objectives of this shared care model were: (1) the improvement of glycaemic control of patients, (2) the efficient provision of diabetes care for patients, (3) the improvement of quality of life of patients as well as (4) their levels of satisfaction with respect to diabetes care.

In order to assess if the model is justified, evidence about the realisation of objectives (1), (3) and (4) as well as about effects on other relevant patient outcomes were provided by this study. For this purpose selected patient outcomes were evaluated within a 12-month pretest-posttest design, while the subgroup of patients treated with oral hypoglycaemic agents (OHA) and/or insulin was compared with a group from another study directed at outpatients with stable type 2 diabetes (Vrijhoef et al., 2001). An indication for the efficiency of care delivered by the model was based on data from this study as well as from another study on the costs generated by this model (Keijzer, 1999).

PATIENTS AND METHODS

Patients and setting

Patients were recruited from the populations of five general practices (11 GPs) in the region of Venlo between September 1997 and April 1998. Patients with previously documented type 2 diabetes attending the general practice were invited by their GP to participate in the study. Patients were provided with a written description of the study and those who supplied written informed consent were enrolled. After enrolment patients were followed for a period of 12 months. The study was approved by the local scientific and ethical committee.

Study design and procedures

To assess outcomes of care in the new shared care model, a quasi-experimental pretest-posttest design was used (Cook and Campbell, 1979). Before the shared care model was introduced, eligible patients were treated for their diabetes by the GP as main care-provider and some additionally by the endocrinologist, while consultations with other care-providers were organised via the GP.

In the shared diabetes care model, the GP refers patients with type 2 diabetes to the specialised nurse from whom they receive regular consultations at the GP's practice. The annual number of consultations depends on the health status of the patient. If necessary, the nurse refers patients to other care-providers involved in diabetes care: the dietician, the diabetes community nurse, the podiatrist, the ophthalmologist and the endocrinologist. The diabetes nurse co-operates closely with other involved

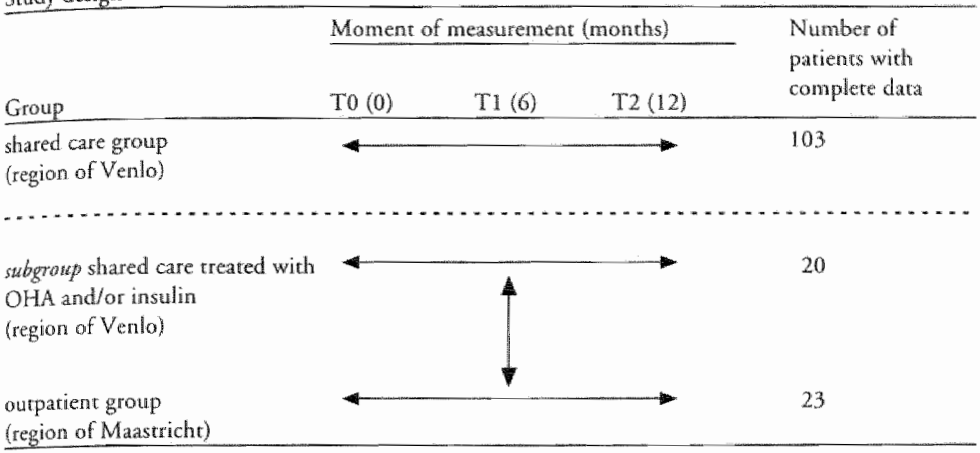
care-providers. The guidelines of the Dutch Colleges of GPs on the management of type 2 diabetes mellitus (Rutten et al., 1999), which have been drawn up in accordance with international guidelines, were used as a reference for the jointly formulated protocol in which tasks, activities and responsibilities of all care-providers involved as well as their interrelations were laid down.

Tasks (activities) of the diabetes nurse comprised the following: direct patient care (medical history, physical examination, interpretation of laboratory results, administration of findings); co-ordination and organisation of care (identification of shortcomings in care, referral to and communicating with other care-providers); consultation (advice to patients and other care-providers); and advancement of expertise (education of patients, themselves and other care-providers). The diabetes nurse has the highest qualification level for nursing care and is seen as a nurse specialist who is focused on diabetes care and who possesses quite distinctive skills in this area of practice (Barton et al., 1999). The role of the GP in the new model of diabetes care is confined to performing one annual consultation, controlling the management of the diabetes of patients, being available on demand for the diabetes nurse in case of irregularities, and having final responsibility for the diabetes care. The endocrinologist is a consultant in diabetes care for the diabetes nurse and the GP.

For practical reasons it was not possible to form a control group for assessing the outcomes of the shared diabetes care model in comparison with usual diabetes care. However, the simultaneous start of a study carried out by the university hospital Maastricht, whose aim was to assess effects on patient outcomes when tasks of diabetes care are transferred from endocrinologist to diabetes nurse and also from outpatient to primary care, made it possible to extend the study design to an untreated comparison group design with pretest and posttest (Cook and Campbell, 1979) (Figure 1). In this way an attempt was made, in addition to suggesting hypotheses for further research, to assess and interpret more conclusively the outcomes of the shared diabetes care model.

In the Maastricht study outpatients with stable type 2 diabetes receiving usual diabetes outpatient care were compared with patients who were mainly treated by specialised nurses in general practices (Vrijhoef et al., 2001). In the Maastricht study patients had stable type 2 diabetes when the concentration of glycated haemoglobin (HbA_{1c}) was 10.5% or less for the preceding six months at least, and were free of active diabetes-related complications and free of other diseases not related to diabetes for which care from a medical specialist is received. The control group of the Maastricht study, referred to as outpatient group, was used for making comparisons. Usual outpatient care for patients with stable type 2 diabetes consists of regular consultations by the endocrinologist in the hospital. With usual outpatient care for patients with stable type 2 diabetes being substituted both horizontally and vertically, the outpatient group was considered suitable for comparing outcomes of care.

Figure 1
Study design



All patients from the outpatient group were treated with OHA and/or insulin. With diet, OHA, and insulin being successive steps in glycaemic regulation and thus indicators for the severity of diabetes, the subgroup of patients receiving shared care and also being treated with OHA and/or insulin at baseline was compared with the outpatient group.

Outcome measures

The outcomes identified for this study were derived from the distinctions made by Donabedian (1992), Long et al. (1993) and Driessen et al. (1994), who seem to agree on patient outcomes for evaluation when the goal is to assess the effects of an intervention concerning quality of chronic care. As indicators of effectiveness, clinical parameters, patient satisfaction, quality of life, self-care behaviour and disease specific knowledge were measured, while consultations with care-providers were used as an indicator of efficiency.

Clinical parameters. The main outcome measure was the change in glycaemic control, defined as the change in glycated haemoglobin level (%HbA_{1c}) and measured using standard laboratory measures. For all patients, first and last assessment of HbA_{1c} within the study period were evaluated as were the proportions of patients with good (HbA_{1c}<7.0%), moderate (7.0%≥HbA_{1c}<8.5%) or bad glycaemic control (HbA_{1c}≥8.5%).

Clinical status was also determined by systolic blood pressure, diastolic blood pressure, total cholesterol concentration, high density lipoprotein cholesterol concentration, and triglyceride concentration.

Patient satisfaction. Patient satisfaction was measured by asking patients to grade the received care with a report mark (between 1 for 'low quality of care' and 10 for 'high quality of care'); whether they would recommend the received care to other patients ('yes' or 'no'); and whether they intended to continue using the experienced care in future ('yes,' 'no,' 'no preference'). These items are derived from industrial marketing management and were applied earlier in the same area of research (Cockroft et al., 1987; Grassic, 1994).

Quality of life. Quality of life was defined as health status of patients and measured with the COOP/WONCA charts and a Visual Analogue Scale (VAS), both having proved to be valid instruments (Maxwell, 1978; Nelson et al., 1987; Van Weel, 1993). The charts consist of six single-item measures: physical fitness, feelings, daily activities, social activities, change in health and overall health. Each chart represents a distinct domain, refers to a two-week period, and has a five-point Likert scale where five indicates the worst level. The VAS was used as single-item measure of quality of life. It consists of a 10-centimetre long horizontal line with 'low quality of life' at the left end of the line and 'high quality of life' at the right. For both instruments Dutch versions were used.

Disease-specific knowledge of patients and self-care behaviour. In addition to the stated objectives of the shared care model, two more classic outcomes related to the nurse's interpersonal competence were assessed. Disease-specific knowledge of patients was measured using a Dutch diabetes-specific instrument. This instrument contains 12-multiple choice questions. Each correct answer yields one point and the total score is achieved by summing the correct answers. No data about the reliability of this instrument has been published (Ripken et al., 1990). Reliability analysis on the data of this study yielded a Cronbach's alpha of 0.80.

Self-care behaviour of patients was measured with a Dutch diabetes-specific instrument, the Self-Care Behaviour Checklist (SCBC). The SCBC consists of four factors (18 items): self-regulation (three items); bodily observation and conditioning (three items); recording activity of condition (four items); and diet application and commitment (eight items). Every item consists of a five-point Likert scale ranging from 'never' to 'always.' Scores for each factor were computed (sum divided by range) and also the total score (sum divided by range). The SCBC was found to be a valid instrument to measure self-care behaviour of diabetes patients (Pennings–van der Eerden, 1992).

Improvements in both self-care behaviour and knowledge about diabetes were expected to occur.

Consultations with care-providers. As an indicator of efficiency diabetes-related consultations of patients with care-providers were measured. Patients were asked to record the number of consultations received from diabetes nurse, GP, and/or endocrinologist.

Co-variables. Diabetes treatment and duration of diabetes served as co-variables. Treatment was specified as diet only, diet with OHA, diet with OHA and insulin, and diet with insulin. A switch between these treatment regimes was considered as a change in diabetes treatment.

Clinical data were collected when patients attended the general practice for consultation for a period of 12 months after enrolment of patients. Data regarding other indicators of quality of care were collected with questionnaires immediately prior to introduction of the shared care model (T0), after six months (T1) and after 12 months (T2). Questionnaires were mailed with an explanatory letter to patients in postage-free envelopes. In the Maastricht study identical instruments and moments of measurements were used.

Statistical analysis

Differences between baseline characteristics were tested using chi-square test and Student's t-test for independent samples. To assess differences in clinical parameters within groups Student's t-test for paired data was used. Analysis of covariance (ANCOVA) was performed for between groups comparisons of change in HbA_{1c} with baseline measurement and duration of diabetes as co-variates. Proportions of patients with good, moderate, or bad glycaemic control were compared between first and last measurement with chi-square test.

One factor repeated-measures analysis of variance was used for satisfaction rate, VAS, COOP/WONCA charts, knowledge and self-care behaviour of patients in the shared care group with complete data and within groups treated with OHA and/or insulin. For analysing differences in these outcomes between groups treated with OHA and/or insulin, ANCOVA was used with baseline measurement as co-variate. Comparison of the number of consultations with care-providers within group was performed with Friedman test, while Kruskal-Wallis one-way analysis of variance was used for comparisons between groups treated with OHA and/or insulin.

All data were analysed on the basis of intention to treat: missing responses were estimated using the last observed response (carry forward). A significance level, p=.05 (two tailed), was used. Data processing and analyses were conducted with SPSS (Windows Release 9.0).

RESULTS

Patients

Of the 325 eligible patients identified by the GPs, 150 (46.2%) did not participate. Reasons for non-participation were lack of interest (7.7%), too much trouble (3.4%), several low prevalence reasons (6.5%, made up of: mobility problems (0.9%), feeling too old (0.6%), private reasons (1.5%), admitted to hospital (2.2%), and unwilling to change care-provider (1.2%)) or unknown (28.6%). Data from consultations were available for all 175 participants. Data from questionnaires were available for 155 patients (88.6%) at T0, for 122 patients (69.7%) at T1, and for 103 patients (58.9%) at T2. Main reasons for not returning the questionnaires were loss of interest and antipathy to completing them.

The basic characteristics for patients of whom complete data were available were compared with patients for whom data from questionnaires at T0, T1 and/or T2 were missing (Table 1). Patients with missing data from questionnaires had suffered from diabetes on average four years longer, had worse glycaemic control, and were less often married than patients with complete data. The basic characteristics for patients from the shared care subgroup with complete data were also compared with patients from the outpatient group with complete data.

Outpatients were on average 5.4 years older than patients from the shared care subgroup. Patients from the outpatient group with complete data differed from outpatients without complete data by having worse glycaemic control (no data given).

Clinical parameters

Mean HbA_{1c} of patients from the shared care group improved statistically significantly by 0.3% to 7.7% (Table 2). Improvement of mean HbA_{1c} was found in the group of patients with missing data (0.3%) and in the group of patients in whom diabetes therapy was unchanged (0.2%). Between subgroups no statistically significant differences in change in HbA_{1c} were found. The proportion of badly regulated patients (HbA_{1c} >8.5%) decreased by 6.3% to 20.3% in the shared care group, by 13.1% (to 30.4%) and 5.2% (to 18.5%) in the group of patients with changed and unchanged diabetes therapy respectively, by 7.9% (to 42.1%) in the shared care group treated with OHA and/or insulin, while in the outpatient group an increase of 10.9% (to 52.2%) appeared. In all (sub)groups the distribution of patients according to level of diabetes control changed statistically significantly between first and last measurement favourably except for the outpatient group in which after one year follow-up fewer people showed good or moderate glycaemic control.

Table 1
Baseline characteristics of all patients, patients with complete data or missing data (shared care group) and outpatient group with complete data

Variable	shared care group				outpatient group with complete data	p-value[b]	p-value[c]
	all	missing data	complete data	complete data and treated with OHA[a] and/or insulin			
	n=175	n=72	n=103	n=20	n=23		
Sex (% men)	50.9	45.8	54.4	45.0	45.5	0.266[d]	0.976[d]
Mean age ± sd (years)	64.1 ± 11.5	64.8 ± 12.1	63.5 ± 11.1	63.7 ± 8.1	69.1 ± 7.3	0.485[e]	0.026[e]
Marital status							
% married	66.0	50.9	73.8	75.0	81.8		
% divorced	7.7	13.2	4.9	5.0	0.0		
% widowed	17.3	24.5	13.6	15.0	18.2		
% never been married	9.0 [156]	11.3 [53]	7.8	5.0	0.0 [22]	0.031[d]	0.508[d]
% Living alone	28.8 [156]	37.7 [53]	24.3	20.0	9.1 [22]	0.083[d]	0.260[d]
% Privately insured	22.0 [150]	14.6 [48]	25.5 [102]	5.0	25.0 [20]	0.133[d]	0.077[d]
% Member of patient association	14.5 [152]	10.2 [49]	16.5	25.0	13.6 [22]	0.302[d]	0.349[d]
Mean duration of diabetes ± sd (years)	9.4 ± 9.8 [162]	11.8 ± 12.5 [62]	7.9 ± 7.3 [100]	14.1 ± 8.1 [18]	14.1 ± 8.7 [22]	0.013[e]	0.994[e]
Therapy (%)							
diet	13.1	11.1	14.6	-.-	-.-		
OHA[a]	61.7	55.6	66.0	-.-	-.-		
OHA[a] + insulin	2.9	5.6	1.0	5.0	18.2		
insulin	22.3	27.8	18.4	95.0	81.8	0.116[d]	0.188[d]
Mean HbA_{1c} ± sd (%)	8.0 ± 1.5	8.4 ± 1.7	7.7 ± 1.2	8.6 ± 1.4 [19]	8.5 ± 1.1 [22]	0.001[e]	0.851[e]

[ ] number of patients for whom data were used in case data were not available for entire group; [a]oral hypoglycaemic agents; [b]significance level of test between patients from shared care group with and without complete data; [c]significance level of test between shared care group with complete data and treated with OHA and/or insulin and outpatient group with complete data; [d]Likelihood-ratio chi square test;[e]t-test

Table 2
Effects in glycaemic control (%HbA_{1c})

Group of patients	n	first measurement (mean ± sd)	last measurement (mean ± sd)	p-value within group	last–first measurement (mean ± sd)	p-value[a] between groups
shared care	158	8.0 ± 1.5	7.7 ± 1.3	0.001	-0.3 ± 1.0	-
complete data	98	7.6 ± 1.2	7.4 ± 1.0	0.069	-0.2 ± 0.1	
missing data	60	8.3 ± 1.6	8.0 ± 1.4	0.004	-0.3 ± 0.8	0.511
changed therapy	23	8.7 ± 1.6	8.2 ± 1.5	0.081	-0.5 ± 1.3	
unchanged therapy	135	7.7 ± 1.3	7.6 ± 1.1	0.010	-0.2 ± 0.8	0.851
shared care (OHA/insulin)	38	8.8 ± 1.4	8.4 ± 1.3	0.008	-0.4 ± 1.0	
outpatient care	46	8.2 ± 1.1	8.5 ± 1.3	0.005	+0.3 ± 0.8	0.001

[a] corrected for baseline value of HbA_{1c} and duration of diabetes.

Table 3
Outcomes within shared care group

Outcome (min-max)	n	measurement (mean ± sd)			p-value	F-statistic
		T0[a]	T1[b]	T2[c]		
Satisfaction						
Satisfaction rate (0–10)	95	8.0 ± 1.3	8.2 ± 1.0	8.1 ± 1.0	0.308[d]	1.175
Quality of life						
VAS (0–10)	100	5.4 ± 2.5	5.3 ± 2.5	5.7 ± 2.4	0.249	1.401
Physical fitness (5–1)	98	2.6 ± 1.3	2.5 ± 1.3	2.7 ± 1.3	0.598	0.516
Feelings (5–1)	101	2.2 ± 1.2	2.1 ± 1.0	2.2 ± 1.2	0.502[d]	0.673
Daily activities (5–1)	101	2.0 ± 1.1	2.1 ± 1.1	2.1 ± 1.0	0.569	0.565
Social activities (5–1)	100	1.8 ± 1.1	1.9 ± 1.1	1.9 ± 1.0	0.286	1.260
Change in health (5–1)	100	2.7 ± 0.7	2.7 ± 0.8	2.8 ± 0.8	0.525	0.647
Overall health (5–1)	102	3.1 ± 0.9	3.2 ± 1.0	3.2 ± 1.0	0.671	0.399
Knowledge and self-care behaviour						
Knowledge (0–12)	103	7.1 ± 3.3	8.0 ± 3.1	7.9 ± 3.1	0.000	8.799
Diet application (1–5)	73	3.5 ± 1.0	3.5 ± 0.9	3.4 ± 0.9	0.766	0.267
Self-regulation (1–5)	47	3.4 ± 1.2	3.9 ± 1.1	3.9 ± 1.2	0.012	4.619
Activity of condition (1–5)	76	2.9 ± 1.3	2.5 ± 1.1	2.7 ± 1.2	0.007	5.141
Bodily observation and conditioning (1–5)	81	3.3 ± 1.3	3.5 ± 1.3	3.8 ± 1.2	0.000	8.092
Overall self-care behaviour (1–5)	21	3.4 ± 0.7	3.4 ± 0.8	3.4 ± 0.6	0.851	0.162

[a]T0 baseline; [b]T1 first post measurement; [c]T2 second post measurement; [d] Greenhouse-Geisser adjusted univariate approach

The mean HbA_{1c} of patients treated with OHA and/ or insulin and receiving shared care showed a statistically significant improvement of 0.4% to 8.4%, while in the group of outpatients the mean HbA_{1c} deteriorated statistically significantly by 0.3% to 8.5%. This difference in change was found to be statistically significant when corrected for baseline HbA_{1c} and duration of diabetes.

In the shared care group improvements were found in mean diastolic blood pressure, by 4.0 mmHg to 80.6 mmHg (n=124; p=.000), in total cholesterol concentration, by 0.1 mmol/l to 5.6 mmol/l (n=130; p=.048), and in the concentration of triglyceride, by 0.2 mmol/l to 1.8 mmol/l (n=128; p=.005). A statistically significant difference (p=.016) was found between groups for change in systolic blood pressure: an improvement of 5.1 mmHg was found in the group with complete data (n=80), while a deterioration of 4.5 mmHg was found in the group with missing data (n=31). Due to insufficient data about blood pressures and lipids of outpatients, no analyses between the shared care group and outpatient group could be performed for these clinical parameters.

Patient satisfaction

Mean satisfaction rates of patients receiving shared care were high and fairly stable (Table 3). The mean rate at T0 reflects satisfaction of patients with traditional care, while mean rates at T1 and T2 reflect patient satisfaction with the shared care model. The comparison of the subgroup treated with OHA and/or insulin with the outpatient group also showed mean satisfaction rates around the value of eight for all measurements, indicating high mean satisfaction of patients with received care. No statistically significant changes were found either within or between groups.

At baseline 96% of patients (n=95) stated they would recommend traditional care to others. After having received shared care, 97% of patients at both T1 and T2 would recommend shared care. When patients (n=98) were asked if they would make use of care in the future, at T0 97% said they would use traditional care. After having received shared care, at T1 64% of patients said they would use shared care in the future, while 33% of patients showed no particular preference between traditional care and shared care. At T2 these percentages were 76% and 12% respectively.

As for recommending care to others when the subgroup treated with OHA and/or insulin (n=19) was compared with outpatients (n=21), 95% or more of patients in both groups for all moments of measurement said they would do so. As for making future use of traditional care for all measurements the entire outpatient group (n=21) said they would. The same was seen at baseline in the shared care group (n=20), while at T1 60% said they would make use of shared care in the future and 35% showed no preference. At T2 these percentages were 75% and 10% respectively.

Quality of life

On the VAS for quality of life amongst patients, no statistically significant changes were found in the shared care group (Table 3). Means were slightly above the middle of possible values. The subgroup of patients treated with OHA and/or insulin showed mean scores under the middle of possible values for all measurements. Within and between the subgroup treated with OHA and/ or insulin and the outpatient group, no statistically significant differences were found.

With regard to the COOP/WONCA charts, fairly steady mean values were found for all scales in the shared care group (Table 3). None of the changes found was statistically significant. Patients treated with OHA and/ or insulin showed mean scores that were fairly similar to entire shared care group on all charts. Within the subgroup receiving shared care and treated with OHA and/or insulin, a statistically significant deterioration was found in change in health ($F=4.065$; $p=0.026$). Within the outpatient group no changes were found. No changes were found between the groups treated with diabetes medication.

Disease-specific knowledge of patients and self-care behaviour

Patients receiving shared care showed a statistically significant improvement in their mean level of knowledge about diabetes during the study (Table 3). Means with respect to the diabetes knowledge of patients treated with OHA and/or insulin were higher than for the entire shared care group. When the subgroup of patients receiving shared care and treated with OHA and/or insulin was compared with outpatients no statistically significant changes within or between groups were found.

With regard to self-care behaviour in the shared care group, statistically significant improvements were seen in means for self-regulation and for bodily observation and conditioning, while a statistically significant deterioration was seen in activity of condition (Table 3). Activity of condition deteriorated between baseline and first post measurement, but improved towards the end of the study. Improvement here means more frequent performance, while deterioration means less frequent performance. Data required to assess overall scores in self-care behaviour could only be obtained for 21 patients. No change was seen in overall score. When the subgroup of patients receiving shared care and treated with OHA and/or insulin was compared with the outpatient group for self-care behaviour, higher means were shown at baseline for self-regulation and bodily observation than for the entire shared care group. No statistically significant changes were found within or between groups.

Table 4
Consultations of patients with care-providers

Outcome	n	measurement (mean ± sd)			chi-square	p-value
		T0[a]	T1[b]	T2[c]		
Consultations with care-providers						
Consultations with diabetes nurse	87	0.6 ± 1.3	2.0 ± 1.2	1.7 ± 1.7	60.316	0.000
Consultations with general practitioner (GP)	90	1.3 ± 1.3	1.7 ± 1.6	1.2 ± 1.1	7.977	0.019
Consultations with endocrinologist	93	0.2 ± 0.6	0.2 ± 0.6	0.2 ± 0.6	1.914	0.384
Consultations with diabetes nurse + GP + endocrinologist	85	1.9 ± 1.9	4.0 ± 2.8	3.1 ± 2.3	45.452	0.000

[a]T0 baseline; [b]T1 first post measurement; [c]T2 second post measurement

Consultations with care-providers

The pattern of consultations of patients in the shared care group showed a statistically significant increase in mean number of consultations with the diabetes nurse, with fairly stable means for number of consultations with the endocrinologist (Table 4). The number of consultations with the GP increased from baseline to T1 and decreased back to baseline level at T2. Overall mean number of consultations increased from baseline to T1 and remained statistically significantly higher.

When the subgroup of patients receiving shared care treated with insulin and OHA was compared with the outpatient group, a statistically significant difference was found in the mean number of consultations with the diabetes nurse between groups, with an increase in the shared care group. The groups also differed for mean number of consultations with the endocrinologist, with higher consumption in the outpatient group. For the number of consultations with all three care-providers, it was found that the statistically significant difference between groups at baseline, with a smaller mean consumption in the shared care group, disappeared at T2.

DISCUSSION

The effectiveness of new models for chronic care has largely gone untested (Davis et al., 1999). In this study, evidence about a shared care model for patients with type 2 diabetes was gathered when the diabetes nurse is the main care-provider in a primary care setting. Applying a quasi-experimental design, it was found that the glycaemic control, diastolic blood pressure, and the concentration of total cholesterol and triglyceride of patients receiving shared care improved, while quality of life and satisfaction of these patients remained equal when compared with the situation before the

shared care model was introduced. Furthermore, improvements were found in knowledge, self-regulation, and bodily observation and conditioning, while activity of condition increased towards the end after having decreased between start and first post measurement. Overall self-care remained unchanged. Patients reported consulting the diabetes nurse in addition to the GP. Comparisons of the subgroup treated with OHA and/or insulin with an outpatient group – except for blood pressures and lipids – showed better glycaemic control and more consultations with the diabetes nurse as remaining effects.

A review of the literature about care models with the nurse specialist in the central role showed improvements in self-care, quality of life, patient satisfaction and increase in medical consumption depending on the division of tasks between care-providers (Vrijhoef et al., 2000). Improved glycaemic control was found in two trials with the diabetes nurse making follow-up telephone calls (Kirkman et al., 1994; Aubert et al., 1998). The Maastricht study, from which the control group was used, evaluated effects of both horizontal and vertical substitution and showed equal patients outcomes in all except glycaemic control (Vrijhoef et al., 2001). The glycaemic control of patients treated by the diabetes nurse as main care-provider was found somewhat better than that in patients receiving usual outpatient care.

This study has several limitations, the first of which concerns the study population. All patients with type 2 diabetes from the participating GPs received shared care with the nurse as main care-provider. Not all of these patients participated in this study nor provided complete data. The response rate (54%) and completion rate (59%) of the shared care group were rather low, yet not uncommon in current longitudinal studies with the chronically ill. With sponsorship of the questionnaire by the GPs, an explanatory letter, postage-free envelope, as well as reminders, several steps to help increase the response rate were taken. The considerable length of the questionnaire could have put off respondents. The study findings may have been biased, because patients with incomplete data suffered on average longer from diabetes and had worse mean glycaemic control. In addition to estimating the missing responses by imputing the last observed response, reanalyses were performed for the variables with most missing values: patient satisfaction rate, quality of life, knowledge, self-care behaviour, and consultations (data not shown). Missing responses at baseline were replaced by the mean of the group and subsequently carried forward. Reanalyses were performed on the data of 155 patients at three measurements and largely confirmed the research findings. With regard to quality of life a statistically significant deterioration in social activities for the shared care group was found, while between subgroups treated with OHA and/or insulin a statistically significant difference was found for change in health. With regard to self-care behaviour statistical significant improvements were found within the shared care group for activity of condition and bodily observation and conditioning, while a difference was found for the overall score in self-care behav-

iour between the groups of patients treated with OHA and/or insulin. The subgroup of patients receiving shared care showed an improvement in overall score in self-care behaviour, while the outpatient group showed a deterioration. The applicability of our findings to all patients with (type 2) diabetes being treated in primary care requires further study.

A second limitation is the applied study design. With regard to research about the effectiveness of complex interventions like the shared care model assessed here, the randomised controlled trial as ideal design could not be met. To strengthen the evidence of the outcomes of the shared care model under real life conditions, Van Weel and Knottnerus (1999) proposed the use of alternative designs. Within the restrictions we met, use was made of a twelve-month one-group pretest-posttest design with additional comparisons for the subgroup of patients treated with oral hypoglycaemic agents and/or insulin with patients from the control group of a study directed at outpatients with stable type 2 diabetes. Treatment with insulin is the last step in glycaemic control and, as advised by the guideline (Rutten et al., 1999), GPs often make use of secondary care when therapy with insulin is appropriate. This explains the relatively small size of the subgroup of patients treated with OHA and/or insulin in the primary care setting considered in this study. Notwithstanding the size of groups compared and thus the difficulty for assessing effects, not performing the comparison would certainly leave the findings of the pretest-posttest design hard to interpret.

Since data about glycated haemoglobin were available for all patients who responded, one can have reasonable confidence in the improved glycaemic control found in the entire shared care group as well as in the subgroup treated with OHA and/or insulin. Improved glycaemic control can be obtained by life-style changes and/or through therapy (Fisher et al., 1997). With no difference in the effect on HbA_{1c} between patients with unchanged and changed diabetes therapy, the effects may most probably be ascribed to life-style changes recommended and/or reinforced by the main care-provider, the diabetes nurse. This supposition seems reasonable with the improvements in knowledge, self-regulation, and bodily observation and conditioning found in the shared care group. These improvements did not remain in the subgroup treated with OHA and/or insulin, but were more difficult to find because of the small group size. Moreover, baseline means for knowledge and self-care behaviour of patients treated with diabetes medication were more or less equal to that of the entire shared care group at final measurement. Changed diabetes therapy in this study means a transition between the existing modes of therapy. When receiving diabetes medication, a change in dose is the most accurate measurement for change in therapy. No statistically significant correlation between change in HbA_{1c} and change in doses of OHA and/or units of insulin was found in the groups treated with diabetes medication.

Although the exact clinical magnitude of the improved glycaemic control in patients as found in this study is hard to express, any improvement in glycaemic control across the diabetic range is likely to reduce the risk of diabetic complications. Moreover, the lower the glycaemia the lower the risk of complications (Stratton et al., 2000). Furthermore, when patients suffer less from diabetic complications, their quality of life scores are expected to improve as well. Future research should address this relation as well.

Without data about blood pressures and lipids from the outpatient group, the differences found in these clinical parameters in patients receiving shared care are hard to interpret. In the earlier mentioned trials with the diabetes nurse making follow-up telephone-calls no differences in blood pressures or lipids were found between groups (Kirkman et al., 1994; Aubert et al., 1998). The application of electronic patient records might result in a more complete clinical data set and enable statistical analysis.

The instrument applied to assess self-care behaviour of patients also limits the results of this study. The overall score could only be assessed for a minority of the patients because sub-scales were not administered completely. The SCBC has recently been simplified but its psychometric qualities remain unknown (Van den Arend et al., 2000). More research should be initiated into psychometric characteristics of existing instruments to measure self-care behaviour of (Dutch) diabetes patients or perhaps even into the development of new instruments.

A fifth limitation of the study is related to the measurement of consultations of patients with care-providers. Some patients appeared to consult the diabetes nurse at baseline, so before the introduction of the new shared care model. The most reasonable explanation is confusion among patients about the role performed by the nurse. With the same person working as practice nurse before introduction of the new model and as diabetes nurse after, it was at least at baseline unclear for patients that the same person performed different roles in care. In a study about the direct medical costs of this shared care model the time-span of consultations as well as time-prices were assessed (Keijzer, 1999). Keijzer (1999) reported that there was no difference in direct medical costs between traditional diabetes primary care and new shared care. The consultations of patients with GPs in the shared care model seem to be shorter than before introduction. With only data about medical consumption and direct medical costs, a well-founded basis for assessing the cost effectiveness of the shared care model is lacking. This issue also needs to be addressed in future research.

In the evaluated model the diabetes nurse is taking on roles and tasks beyond those traditionally performed by physicians. By allocating tasks and responsibilities the relationship between the GP and the diabetes nurse is one of partnership. Patient outcomes were equal to or better than pre-existing care arrangements. There is no single diabetes management model to be applied everywhere, but this study clarifies that the substitution of tasks from physician to diabetes nurse seems to be justified in

terms of patient outcomes and can be part of such a model. Nevertheless, for (broader) implementation of the nurse specialist in diabetes care, several difficulties like educational preparation for undertaking the role of nurse specialist, appropriate salary, professional collaboration, and evaluation and quality control need to be addressed.

The evidence from this study seems to justify continuation of a model of shared diabetes care with the diabetes nurse as main care-provider for patients with type 2 diabetes in a primary care setting. High quality care was safeguarded, while future research should provide evidence about the cost-effectiveness. With the continuous rise in the need for chronic disease management the pressure will increase on nurses to deliver that care. When non-physicians are assigned the responsibilities for chronic care, their roles extend, and new models of multi-professional team-working which meet the needs of the growing number of chronically ill people become available.

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6 CHAPTER

Transfer of care for outpatients with stable Chronic Obstructive Pulmonary Disease (COPD) from pulmonologist to nurse specialist: A randomised controlled study

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Based on paper submitted for publication.

ABSTRACT

Objective. To assess effects on patient outcomes when care for patients with stable COPD is transferred from pulmonologist to nurse specialist.
Design. Randomised controlled trial.
Setting. Respiratory outpatient clinic of a general and teaching hospital in Alkmaar, the Netherlands.
Subjects. Of 720 patients, 187 were eligible for randomisation and gave informed consent; 93 patients received care from the nurse specialist and 87 received usual care. Clinical data were analysed for 91 patients in intervention group and for 83 patients in the control group, data from questionnaires for 84 patients receiving care from the nurse and for 75 patients receiving usual care.
Main outcome measures. Clinical parameters, health status, self-care behaviour (including knowledge), patient satisfaction, consultations with main care-providers.
Results. The nurse specialist reported more consultations than the pulmonologist (mean (SD)): number of consultations 3.1(0.7) by nurse and 2.0(0.9) by pulmonologist. Patients cared for by the nurse showed worsening in mean forced vital capacity (-5.5%(13.3%) vs +2.9%(18.2%) with pulmonologist), indifference in self-assessed condition (0.0(1.6) vs +0.6(1.6) with pulmonologist), while improvements were found for subjective knowledge (+2.3(4.0) vs +0.6(3.7) with pulmonologist), self-assessed rate for coping with COPD (+0.3(1.3) vs -0.1(1.4) with pulmonologist), overall satisfaction (+0.5(1.5) vs -0.1(1.2) with pulmonologist), and for the majority of individual indicators of satisfaction. Groups were indifferent for FEV_1, BMI, smoking status, health status, objective knowledge, other items of self-care behaviour, and consultations with main care-providers.
Conclusions. Assignment of care for outpatients with stable COPD to the nurse specialist, working under a protocol, seems to be justified in terms of patient outcomes.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is one of the leading causes of morbidity and mortality world-wide and will rise in the rankings of both measures in the future (Lopez & Muray, 1998). COPD is characterised by the progressive development of airflow limitation that is not fully reversible (Barnes, 2000). COPD is stable when the patient is either symptom-free or has symptoms without substantial fluctuation (Madison & Irwin, 1998). The aims of the management of stable COPD are to improve symptoms and quality of life, to reduce the decline of lung function, to prevent and treat complications, to increase survival with maintained quality of life, and to avoid or minimise adverse effects of treatment (Siafakas et al., 1995).

In the care of chronically ill patients, the role of nurse specialists is growing in importance. Nurse specialists receive master's level training in single specialties, while they have the authority to practice independently under supervision from a physician. As one of the first hospitals in the Netherlands, Medisch Centrum Alkmaar placed the nurse specialist in a central role in the management of the growing number of patients with stable COPD. In this role the nurse specialist is taking on tasks and roles traditionally regarded as the remit of the pulmonologist, allowing physicians to shift the balance of their activities towards managing patients with the most 'serious' health problems. This transfer of care is a case of vertical substitution: a transfer of tasks between care-providers across different levels of expertise (Spreeuwenberg, 1994). Despite the popularity of nurse specialists performing a new role in chronic care, evaluation studies regarding outcome and/or process variables are limited due to the -as yet- underdeveloped nature of this field of study (Wilson-Barnett & Beech, 1994; McGillis Hall, 1997; Temmink et al., 2000; Vrijhoef et al., 2000; Laurant et al., 2002; Loveman et al., 2002).

This study was performed to assess effects on quality of care in terms of patient outcomes, when care for patients with stable COPD is transferred from the pulmonologist to the nurse specialist. It was hypothesised that the nurse specialist, working under a protocol, can achieve patient outcomes at least equivalent to those achieved by the pulmonologist providing usual respiratory care.

METHODS

Patients and setting

This study was performed in the respiratory outpatient clinic of Medisch Centrum Alkmaar, a general and teaching hospital in an urban district with about 240,000 residents. Patients were recruited between January and July 1999 and, if eligible, followed for nine months.

Patients with previously documented COPD attending the respiratory outpatient clinic were invited by their pulmonologist to participate in the study when they had a forced expiratory volume in one second (FEV_1) between 40% and 80% of predicted value (postbronchodilator). Patients were not eligible if they were known to have had more than three exacerbations in the 12 months preceding the study, if they were using oxygen, if they were suffering from another disease not related to COPD for which they were receiving care from a medical specialist, if they had a known arterial carbon dioxide tension ($PaCO_2$) of 6.7 kPa or higher, or if they lacked sufficient mastery of the Dutch language. Eligibility was assessed by the pulmonologist when patients attended the outpatient clinic for scheduled consultation.

Considering the multiple and diverse aims of the management of stable COPD (Siafakas et al., 1995) as well as the nature of the intervention, i.e. a complete transfer of care, no primary outcome measure was selected for the purpose of a power calculation. Patients were provided with a written description of the study and those who supplied written informed consent were enrolled. The study was approved by the local ethics committee.

Study design and procedures

Eligible patients were randomised by means of a computer-generated list of random numbers immediately after consenting to participate in the study. Neither the patient nor the members of the study team were aware of the treatment assignment until after randomisation. The study treatment consisted of outpatient appointments with the nurse specialist as main caregiver, while patients assigned to the usual care group received routine respiratory outpatient care provided by the pulmonologist. When allocated to the intervention group, formal transfer of the patient from pulmonologist to nurse specialist took place.

The nurse specialist was trained to perform routine consultations. Tasks (activities) of the nurse specialist were:

- direct patient care (medical history taking, physical examination, interpretation of tests, administration and assimilation of findings);
- organisation and co-ordination of care for individual patients (identification of shortcomings in care, referral to and communication with caregivers);
- consultation (providing advice to patients and other caregivers);
- promotion of expertise (education of patients, themselves and other caregivers).

Patients in the intervention group received quarterly consultations from the nurse specialist in the outpatient clinic. If complications arose, the nurse could consult the pulmonologist. Final responsibility for the care provided remained with the pulmonologist. The delivery of care was negotiated with all parties involved in respiratory care before the study began and strictly formulated in a protocol.

Patients assigned to the usual care group received follow-up consultations from their pulmonologist at the outpatient clinic. The minimum frequency of planned follow-up consultations in usual respiratory outpatient care is annual, while the pulmonologist may plan follow-ups as frequently as quarterly when indicated. Routine management involved the tasks and activities transferred to the nurse specialist and outlined above.

The duration of the consultations differed between the two groups. Initial consultations with the respiratory nurse could last up to 30 minutes, while follow-up consultations lasted 15 minutes. A consultations by the pulmonologist takes 10 minutes.

Selected indicators of quality of care are considered essential when looking at outcomes in quality of care research for chronically ill (Donabedian, 1992; Long et al., 1993; Driessen et al., 1994). These are clinical parameters, health status, self-care behaviour (including knowledge), and patient satisfaction. We added number of consultations with main care-providers. Data about clinical parameters, and number of consultations were obtained from the caregivers' registries.

Data about other outcomes were gathered via questionnaires mailed, together with an explanatory letter and a prepaid return envelope, to patients. Number of consultations was measured by a separate questionnaire mailed to patients at entry into the study, three, six, and nine months later. Data about health status, self-care behaviour, and patient satisfaction were measured at entry and six months later. The questionnaire sent at entry included items about socio-demographic characteristics of patients.

Clinical parameters were FEV_1, forced vital capacity (FVC), body mass index (BMI), and smoking status. Airflow limitation was measured by spirometry. The caregiver asked the patient about his/ her smoking status. Body height and weight were measured by the caregiver during consultation. Baseline values were derived from the pulmonologist's records. For this, values measured during the last consultation before the start of this study were used except if these were older than six months.

Generic health status was measured with the Dutch version of the COOP/WONCA charts as generic instrument (Nelson et al., 1987; Van Weel, 1993). These charts assess physical activities, feelings, daily activities, social activities, change in health, and overall health. Each domain is covered by a single question to be answered on a five-point scale and is supported by a pictograph representing the options. The scores are calculated for each chart separately. Disease-specific health status was measured with the St George's Respiratory Questionnaire (SGRQ) (Jones et al., 1992). The SGRQ consists of 76 items and measures three components: symptoms, activities, and impact. It also yields a total score. Scores range from 0 to 100, with a score of zero indicating no impairment.

For the measurement of self-care behaviour a Dutch instrument was used (Deenen, 1996). Objective knowledge was measured by means of 22 questions about COPD (range 0–22, Cronbach's alpha = 0.70). Subjective knowledge was measured by means of six questions indicating the estimation patients make of their amount of knowledge (five-point scale ranging from very little to much, Cronbach's alpha = 0.91). Two self-care dimensions were measured: compliance and condition-maintenance. For compliance patients were asked to give a mark (1–10) for the extent to which they think they keep to prescribed medication and for their way of coping with COPD. In addition, they were asked how frequently they used medication according to the prescription, more than prescribed, or less than prescribed (questions have a five-point

scale ranging from never to always and are expressed as one overall score). Condition-maintenance, the extent to which the patient actively works on maintaining a good physical condition, was measured with five items. Patients were asked whether they participated in active movement during their free time (five-point scale ranging from never to very often) and whether they participated in sports (yes/no). Furthermore, they were asked about their daily pattern of movement by asking whether they generally sit, stand, walk, carry heavy subjects, and whether they are tired in the evening (questions have a five-point scale ranging from never to always and are expressed as one overall score). Patients were asked to compare their daily activities with peers (five-point scale ranging from much less difficult to much more difficult) and to give a mark (1–10) for the extent to which they think they maintain their physical condition.

Patient satisfaction was measured using a selection of questions out of a previously validated instrument (Wensing et al., 1996). Because the original instrument was developed for general practice (containing nine dimensions with 51 indicators), dimensions as well as indicators judged as irrelevant for outpatient pulmonary care were not used in this study (the dimensions availability for emergencies, premises, and co-operation). For each dimension the indicators with the highest factor loading were selected. Patients were asked about six dimensions consisting of 20 indicators for quality of care (six-point scale ranging from poor to excellent). Furthermore, patients were asked to grade their satisfaction with a mark (1–10), if they would recommend the care they had received to other patients (yes/no), and if they intended to continue making use of received care in the future (yes/no/no preference). These items are derived from industrial marketing management and have been applied earlier in the same area of research (Littlejohns et al., 1991; GRASSIC, 1994; Shum et al., 2000).

Number of consultations with main care-providers comprised questions about the number of consultations for COPD at the outpatient clinic – with the pulmonologist or nurse specialist – , with the general practitioner, and with the physiotherapist.

Statistical analyses

All the analyses presented were based on intention to treat, while missing response was handled by using the last observed response (carry forward procedure) (Hollis & Campbell, 1999). Groups were compared for baseline characteristics using chi-square test and independent sample t-test. Baseline values of clinical parameters were derived from patient records kept by pulmonologists. Student's t-test for independent samples was used to assess differences between groups in FEV_1, FVC, BMI, COOP/WONCA charts, SGRQ-scales, knowledge, and self-care behaviour scores. For smoking status and indicators of satisfaction proportions were calculated and compared between groups at baseline and at post-measurement with Pearson chi-square. Comparison of

the number of consultations with main care-providers was performed with Kruskall-Wallis one-way analysis of variance. A significance level, p=0.05 (two-tailed) was used. Data processing and analyses were conducted with SPSS (Windows Release 10.0).

RESULTS

Patients flow and follow up

The study sample was recruited from 720 patients who consulted the pulmonary department for their COPD between January and July 1999 (figure). A total of 187 patients met the inclusion criteria as assessed by the pulmonologists and was invited to participate in the study. Ninety-four patients were randomised to treatment by the nurse specialist and 93 patients to treatment by the pulmonologist. Of patients randomised to the nurse specialist 93 (99%) patients received care with 84 (90%) of them returning all questionnaires. Of patients randomised to the pulmonologist, 86 (92%) patients received usual outpatient care and were followed in this study, with 75 (87%) of them returning all questionnaires.

Four patients allocated to the control group and diagnosed with cancer were wrongly assessed for eligibility. Shortly after randomisation one patient allocated to the control group died and one patient moved away. To the intervention group one patient with asthma was wrongly allocated. Baseline comparisons of groups were performed for the patients including those who withdrew after randomisation or moved away (intervention group n=93, control group n=87), but excluding the patients who were lost for other reasons. It seems unlikely that the exclusion of these patients could have affected the study results, because these patients required different care than the care patients with stable COPD receive in daily practice.

Data on clinical parameters were analysed for the patients who received care, excluding those who withdrew their informed consent as well as those for whom recent data on clinical parameters at baseline were not available (nine patients in the intervention group, two patients in the control group). Of patients followed up in the intervention group one died of cancer. This patient and six other patients of the intervention group and eight patients of the control group did not return all questionnaires. However, except for the patient who died, the other 14 patients consulted the caregiver allocated to. The two groups did not differ for main characteristics at baseline (Table 1).

Figure
Trial profile

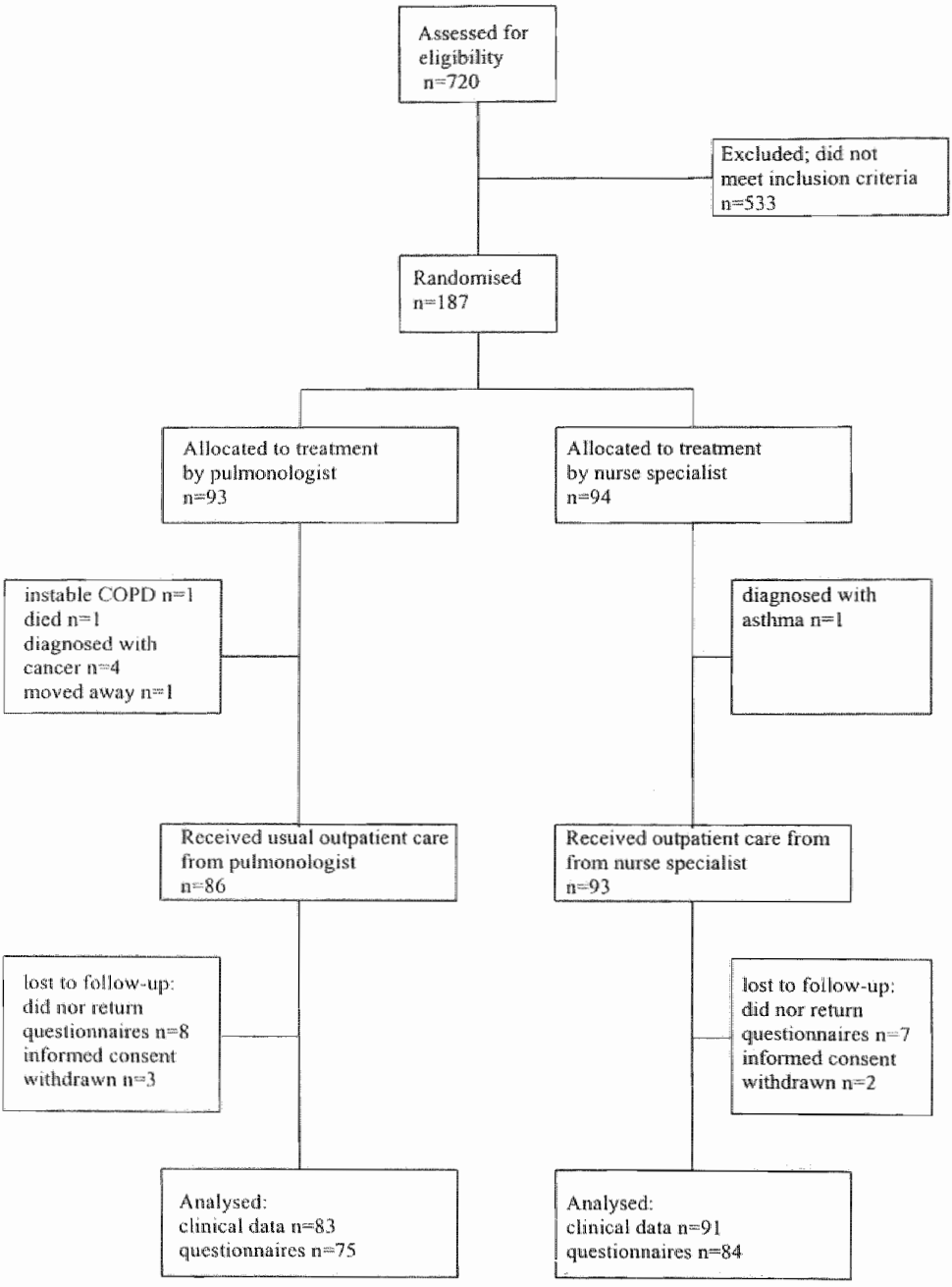

Table 1
Baseline characteristics of patients

Variable[#]	n	Control group	n	Intervention group
Female/male (%)	87	51.7/48.3	93	39.8/60.2
Age (yrs)	87	64.4 ± 10.5	93	64.4 ± 10.2
Time since diagnosis COPD (yrs)	86	7.7 ± 6.2	83	9.1 ± 8.2
Current smoker (%)	86	24.4	84	33.3
FEV_1 (% predicted value)	84	57.7 ± 16.8	84	56.8 ± 15.2
FVC (% predicted value)	84	84.6 ± 18.6	84	85.0 ± 17.5
Body Mass Index (kg/m^2)	82	26.1 ± 5.4	82	25.9 ± 4.0
Marital status (%)	74		89	
Married		68.9		70.8
Divorced		12.2		9.0
Widowed		16.2		13.5
Never been married		2.7		6.7
Living alone (%)	71	21.1	87	20.7
Privately insured (%)	73	30.1	85	22.4
Employed (%)	72	12.5	89	16.9
Member patient association (%)	68	8.8	82	8.5

[#]values are mean ± standard deviation unless stated otherwise

Patient outcomes

Of patients in the intervention group who gave informed consent (n=91) on average 3.1±0.7 consultations with the nurse were registered, with two patients consulting the nurse once. The mean number of registered consultations with the pulmonologist by patients who received usual care and who gave informed consent (n=83) was 2.0±0.9. Groups differed statistically significantly (t=8.93; p=0.00) for the mean frequency of consultations with the main care-provider. Of patients who received usual care, 23 patients consulted the pulmonologist once during the study period. Additional analyses were performed to compare patients who received one consultation with those who received two or more consultations on clinical parameters.

Differences were found for FEV_1 and BMI, with mean scores in favour of patients with one consultation only (ΔFEV_1=8.3%; ΔBMI=2.8 kg/m2).

Only for patients with at least two consultations were effects on clinical parameters analysed (Table 2). No differences were found between subgroups for FEV_1, FVC, or BMI at baseline, while groups differed for change in FVC. In the intervention group mean FVC deteriorated by 5.5%, compared with an improvement of 1.1% in the control group. In the intervention group the proportion of patients who reported

smoking decreased by 4.8% to 29.3% (n=24) between first and last consultation, against an increase in the control group of 1.7% to 23.3% (n=14). Groups did not differ statistically significantly for smoking status at baseline nor at post-measurement.

With regard to health status of patients, steady mean values were found for scales measured with COOP/WONCA charts as well as for scales measured with SGRQ (Table 3). None of the changes between groups was found to be statistically significant.

The questions about patients' knowledge about COPD were incompletely answered by a significant part of both the intervention group (objective knowledge) and the control group (objective and subjective knowledge) (Table 4). No change was seen between groups in objective knowledge of patients about COPD, while means in both groups were slightly higher than half the maximum score. Although patients of both groups reported improvements in subjective knowledge, the improvement for patients cared for by the respiratory nurse was statistically significantly bigger than for patients in the usual care group. Scores for subjective knowledge were slightly above half the maximum score in both groups.

Of indicators measuring self-care behaviour, patients cared for by the nurse showed an improvement in the mark for coping with COPD, while patients cared for by the pulmonologist reported a higher mark for maintaining condition (Table 4). No differences were seen between groups in the changes on the other indicators. For all indicators, groups scored acceptable means.

Although an improvement in the mean rate for satisfaction was found in the intervention group, patients of both groups were almost equally satisfied with the received care (Table 4). When looking at specific indicators for satisfaction (Table 5), no differences in satisfaction with the care provided by the pulmonologist were found between groups at baseline. In both groups the proportion of most satisfied patients was highest for the indicators about continuity and stimulating self-help, while in both groups too the proportion of satisfied patients was lowest for supporting patients' relatives. Towards the end of the study, groups differed statistically significantly for 14 of the 20 indicators in favour of the group cared for by the nurse. No differences between groups were found with regard to recommendation of received care to others and future use of received care (Table 5). In both groups a big majority of patients said they would recommend received care and make future use of it.

Groups were similar in the mean number of reported consultations with main care-providers (Table 6). Nine months after the start of the study groups differed in mean number of reported consultations with the nurse – intervention group – or with the pulmonologist – control group. Although not statistically significant, the control group reported more consultations with the physiotherapist. In both groups the number of reported consultations with the general practitioner decreased towards the end of the study. This was also found for consultations with all three main

Table 2
Effects on clinical parameters for patients with at least two consultations

Parameter	Control group			Intervention group			*ΔI versus ΔC*
	N	mean ± sd at baseline	change in mean ± sd	N	mean ± sd at baseline	change in mean ± sd	p-value
FEV_1 (%)	59	55.3 ± 15.6	+0.9 ± 6.4	82	56.7 ± 15.3	+1.1 ± 11.3	0.866
FVC (%)	59	83.8 ± 14.2	+1.1 ± 11.3	82	85.2 ± 17.6	-5.5 ± 13.3	0.004
BMI (kg/m^2)	60	25.3 ± 3.9	+0.1 ± 0.8	82	25.8 ± 3.9	0.0 ± 1.0	0.484

Table 3
Effects on health status

Outcome	Control group			Intervention group			*ΔI versus ΔC*
	N	mean ± sd at baseline	change in mean ± sd	N	mean ± sd at baseline	change in mean ± sd	p-value
Generic (COOP/WONCA-chart; lowest score=5, highest score=1)							
Physical fitness	73	2.70 ± 1.21	+0.12 ± 1.12	81	2.59 ± 1.27	-0.16 ± 1.26	0.143
Feelings	73	1.97 ± 1.14	+0.00 ± 0.87	81	1.94 ± 1.21	-0.06 ± 1.11	0.703
Daily activities	74	2.22 ± 1.10	-0.11 ± 1.01	80	2.23 ± 1.06	+0.05 ± 1.17	0.373
Social activities	71	1.92 ± 1.17	-0.13 ± 1.03	81	1.70 ± 0.86	+0.20 ± 1.00	0.050
Change in health	74	2.73 ± 0.78	+0.22 ± 0.94	81	2.86 ± 0.70	+0.04 ± 0.91	0.231
Overall health	73	3.25 ± 0.88	+0.07 ± 0.86	83	3.30 ± 0.82	-0.01 ± 0.77	0.538
Specific (St George's Respiratory Questionnaire; lowest score=100, highest score=0)							
SGRQ symptoms	75	37.7 ± 25.3	-1.3 ± 20.3	84	40.6 ± 23.9	-3.4 ± 20.1	0.502
SGRQ activities	72	40.0 ± 21.2	+0.3 ± 14.4	84	36.3 ± 21.0	-1.5 ± 14.9	0.446
SGRQ impact	69	25.3 ± 16.4	-1.2 ± 10.2	81	22.0 ± 13.2	-0.9 ± 10.1	0.883
SGRQ total	69	32.3 ± 16.6	-0.5 ± 9.6	81	29.7 ± 15.4	-1.6 ± 9.9	0.491

Table 4
Effects on knowledge, self-care behaviour and satisfaction

Outcome	Control group			Intervention group			*Δ versus ΔC*
	N	mean ± sd at baseline	change in mean ± sd	N	mean ± sd at baseline	change in mean ± sd	p-value
Knowledge							
Objective knowledge	62	12.9 ± 3.5	+0.4 ± 2.3	66	13.4 ± 3.5	+0.5 ± 2.4	0.732
Subjective knowledge	52	17.7 ± 4.4	+0.6 ± 3.7	84	17.2 ± 5.3	+2.3 ± 4.0	0.017
Self-care behaviour							
Rate compliance med.	72	8.1 ± 1.8	+0.2 ± 1.6	84	7.9 ± 1.8	+0.1 ± 1.3	0.849
Compliance medication	71	4.5 ± 0.6	+0.1 ± 0.5	83	4.6 ± 0.6	0.0 ± 0.5	0.252
Rate coping with COPD	73	7.5 ± 1.5	-0.1 ± 1.4	82	7.2 ± 1.7	+0.3 ± 1.3	0.045
Active movement	70	3.2 ± 1.1	-0.1 ± 0.9	83	3.1 ± 1.1	-0.1 ± 1.1	0.882
Sporting (%)	68	38.0	-1.4	83	33.7	+6.1	0.579
Daily pattern movement	62	3.0 ± 0.5	0.0 ± 0.3	77	3.0 ± 0.5	+0.1 ± 0.4	0.432
Daily activity peers	71	3.1 ± 0.9	+0.2 ± 1.0	80	3.1 ± 1.0	+0.1 ± 1.0	0.622
Rate maint. condition	74	6.2 ± 2.0	+0.6 ± 1.6	83	6.4 ± 1.5	0.0 ± 1.6	0.042
Satisfaction	70	7.9 ± 1.4	-0.1 ± 1.2	79	7.5 ± 1.6	+0.5 ± 1.5	0.003

Table 5
Effects on patient satisfaction

Indicator	Control group			Intervention group			IG versus CG	
	N	proportion (%)		N	proportion (%)		p-value	
		base	pm		base	pm	base	pm
Appointments								
A	72	61.1	56.9	81	49.4	74.1	0.146	0.026
B	72	66.7	65.3	83	68.7	66.3	0.790	0.897
C	72	48.6	47.2	83	43.4	42.2	0.514	0.528
Continuity								
D	70	65.7	61.4	84	77.4	78.6	0.108	0.020
E	66	74.2	65.2	82	80.5	86.6	0.364	0.002
F	69	73.9	68.1	82	74.4	84.1	0.947	0.020
Effectiveness of care								
G	68	69.1	67.6	82	69.5	86.6	0.958	0.005
H	67	59.7	62.7	84	61.9	60.7	0.783	0.804
I	67	52.2	52.2	82	61.0	56.1	0.284	0.638
Humaneness								
J	67	62.7	59.7	82	58.5	85.4	0.606	0.000
Exploring patients' needs								
K	67	62.7	61.2	83	51.8	78.3	0.181	0.022
L	67	65.7	61.2	84	57.1	78.6	0.286	0.020
M	66	53.0	48.5	83	39.8	74.7	0.106	0.001
Involvement in decisions								
N	66	60.6	59.1	81	56.8	75.3	0.640	0.036
Informativeness								
O	67	62.7	53.7	82	59.8	72.0	0.715	0.021
P	66	63.6	59.1	83	54.2	78.3	0.247	0.011
Stimulating self-help								
Q	66	75.8	69.7	84	75.8	81.0	0.664	0.109
Counseling								
R	69	44.9	40.6	83	37.3	73.5	0.344	0.000
S	67	40.3	38.8	83	33.7	71.1	0.407	0.000
Supporting patients' relatives								
T	65	21.5	20.0	81	22.2	34.6	0.921	0.052
Recommend to others	67	97.0	95.5	78	91.0	94.9	0.136	0.844
Future use	69	100.0	100.0	78	97.4	98.7	0.180	0.345

A Clarity of information; B Telephone accessibility for making an appointment; C Possibilities for getting an appointment quickly; D Possibilities for seeing the same care provider; E Care provider knows which symptoms have been discussed before; F Patient is asked to come back regularly for monitoring; G Care provider tries to reduce symptoms; H Care provider's treatment helps to reduce complaints; I Care provider's treatment helps the patient to feel better for a longer period of time; J Care provider shows personal interest; K Care provider helps to clarify symptoms; L Care provider shows (s)he understand what patient tells; M Care provider involves the patient in looking for an explanation of symptoms; N Care provider discusses treatment options with the patient; O Care provider tells clearly what (s)he is up to; P Care provider gives understandable explanation of the treatment; Q Care provider convinced the patient of following advice; R Care provider helps the patient in dealing with the disease; S Care provider has attention for the consequences of the disease in daily life; T Care provider involves patients' relatives in treatment

Table 6
Consultations by patients of intervention group and control group with care-providers

Care-provider	n	measurement (mean ± sd)				between (chi-square, p-value)							
(Group)		baseline	+3 months	+6 months	+9 months	baseline		+3 months		+6 months		+9 months	
Outpatient clinic													
Intervention group	83	0.9 ± 0.6	1.0 ± 0.7	0.8 ± 0.6	0.8 ± 0.8	0.139	0.710	0.639	0.424	3.160	0.075	7.395	0.007
Control group	68	0.9 ± 0.5	1.1 ± 0.7	0.7 ± 0.7	0.5 ± 0.7								
GP													
Intervention group	82	0.7 ± 1.5	0.5 ± 1.0	0.4 ± 0.9	0.3 ± 0.7	0.320	0.572	0.105	0.746	1.259	0.262	0.682	0.409
Control group	66	0.7 ± 1.1	0.6 ± 1.5	0.5 ± 0.8	0.3 ± 0.6								
Physiotherapist													
Intervention group	79	0.9 ± 4.1	0.8 ± 4.2	0.5 ± 2.4	0.6 ± 3.2	0.155	0.694	1.612	0.204	1.849	0.174	0.488	0.485
Control group	64	0.9 ± 3.5	1.2 ± 3.8	1.2 ± 4.2	1.0 ± 3.2								
All (Outpatient clinic + GP + physiotherapist)													
Intervention group	78	2.5 ± 4.5	2.2 ± 4.4	1.6 ± 2.7	1.6 ± 3.6	0.456	0.499	1.981	0.159	0.095	0.759	1.714	0.191
Control group	64	2.5 ± 3.8	2.9 ± 4.4	2.3 ± 4.6	1.7 ± 3.5								

care-providers together. In the control group fewer visits to the pulmonologist were reported towards the end of the study.

DISCUSSION

This study assessed effects on quality of care when care for outpatients with stable COPD is transferred from pulmonologist to nurse specialist. Compared with patients cared for by the pulmonologist, patients receiving outpatient care from the nurse specialist showed a deteriorated mean FVC, did not report an improved physical condition, but did show improvement in subjective knowledge and satisfaction. Groups were found to be comparable for FEV_1, BMI, smoking status, health status, objective knowledge, and compliance. Based on the consultations reported by primary care-providers, patients cared for by the nurse consumed more consultations whereas no differences in number of consultations were found from questionnaires filled out by patients.

Comparable interventions, evaluated with the randomised controlled trial as study design, were compared in a recent literature review (Vrijhoef et al., 2000). Although seven studies were aimed at patients with respiratory diseases and fulfilled the inclusion criteria of the review, the intervention studied by Littlejohns et al. (1991) mostly resembles this study when considering the tasks performed by the central care-provider. An important difference with the intervention evaluated by Littlejohns et al. (1991) is that in the current study a complete transfer of patients from pulmonologist to nurse specialist took place; in the study by Littlejohns et al. (1991) patients in the intervention group continued with their routine outpatient appointments, while care by a respiratory health worker was provided as well. Comparison of the findings by Littlejohns et al. (1991) with those in this study is hampered by the differing study groups with regard to their pulmonary function as well as by some of the instruments used. Littlejohns et al. (1991) expected reductions in respiratory impairment, disability, and experienced handicap when cared for by a respiratory health worker, while higher survival, more number of consultations, improved quality of life and equity for expected outcomes was found. Patients assessed the nurse specialist working in the substitution based model as more satisfactory than the pulmonologist, while in the complementary model no difference in patient satisfaction was found (Littlejohns et al., 1991). The study by Littlejohns et al. (1991) showed a "useful" complementary model for frail patients, while the current study shows that the substitution based model is a justified alternative for patients with stable COPD.

From the registration of care-providers it was found that for the number of consultations performed, the nurse worked closely to the protocol. The pulmonologists performed on average less consultations, with one consultation for patients in a rela-

tively more stable phase. Reasoned deviation from the protocol seems to be justified, while more research is needed to define the optimal number of consultations for individual patients. Differences exist between the number of consultations registered by care-providers and by patients. A possible explanation for this is the moment when patients completed the questionnaires. Although not recorded, it was experienced that not all patients returned the questionnaire within the offered time frame. This might have influenced the findings in the first three months. From the questionnaires administered by patients, differences between groups in the number of consultations with outpatient care-provider seem to be present towards the end of the study. Future research should address the cost-effectiveness of the intervention evaluated here.

No explanation can be given for the statistically significant, but clinical irrelevant difference between groups in FVC. With comparable outcomes for FEV_1, BMI, smoking status and health status one can have reasonable confidence in the clinical safety of the nurse as main care-provider to patients with stable COPD. Although acknowledging the meaning of exacerbations of COPD as an indicator for the quality of care, this outcome was not assessed because of the absence of a valid and reliable reporting system for exacerbations experienced by patients. Considering the group of patients in this study – stable COPD – one might wonder about the relevance of this parameter here. Moreover, this seems to be confirmed by the comparability of groups in FEV_1, BMI, smoking status, health status, objective knowledge, and consultations with care-providers.

Questions about knowledge might have been too difficult for patients with stable COPD in this study. Because of missing answers, no total score could be computed for 30 and 22 patients of the intervention and the control groups respectively. Moreover, of patients who answered all questions about objective knowledge, the mean score was just slightly above half the maximum score. Six months might be too short to measure an increase with instrument used for objective knowledge, because patients cared for by the nurse estimated their knowledge better at the start than patients in the control group. Higher response on the knowledge questionnaires might be reached when the nurse gathers the answers of patients on the questions during consultation, while after assessment of these data it would enable the nurse to provide the patients with an intervention tuned to the individual patient. With means for subjective knowledge in both groups just above half the maximum score, improving of the knowledge of patients about COPD seems to be a goal in respiratory care.

Assessment of the effects on self-care behaviour was limited by using instruments for just two dimensions. However, internationally valid and reliable instruments to measure self-care behaviour of patients with COPD seem to be lacking. Some changes occurred on indicators of self-care, but groups were fairly comparable at the end of the study with regard to self-care behaviour.

Patients in the intervention groups showed better outcomes for the grade for satisfaction and for the majority of indicators of satisfaction compared with patients in the control group. This outcome seems to make the difference between care with the nurse in a central role and usual outpatient care. While a relationship between length of consultation and patient satisfaction exists, Shum et al. (2000) found that differences in patient satisfaction with nurses and general practitioners remained significant when this was accounted for. Research to the factors leading to this difference as well as to the influence of satisfaction on other outcomes is needed.

In conclusion, this study shows that transfer of care for patients with stable COPD to the nurse specialist is justifiable in terms of patient outcomes. For patients it is acceptable to consult the nurse specialist instead of the pulmonologist. The substitution-based model evaluated is a justified alternative for traditional outpatient care of patients with stable COPD.

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7 CHAPTER

Undiagnosed patients and patients at risk for COPD in primary health care: Early detection with the support of non-physicians

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ABSTRACT

Given the increasingly heavy workload in the primary health care sector, the option of allocating activities involving the management of chronic diseases to non-physicians has recently come under scrutiny. The purpose of this study was to assess the feasibility of the support provided by non-physicians to general practitioners in the early detection of COPD. A convenience sample consisting of two hundred and thirty-one patients (40–70 years; >10 pack years) from eight general practices in the Maastricht region in the southern Netherlands, who consulted their general practitioner for reasons unrelated to respiratory diseases, were assessed for their respiratory function. Prior to the first assessment, patients were interviewed about their medical history and symptoms. By taking the results of the lung function measurement as the starting point, the predictive value of medical history and symptoms in the identification of patients at risk for airflow obstruction or of COPD was assessed and compared with findings in literature.

Seventeen patients (7.4%) were diagnosed with COPD, 11 patients (4.8%) with asthma. In addition to age and moderate smoking history, breathlessness and a history of heavy smoking were identified as risk factors for airflow limitation and COPD. Early detection of COPD in primary health care by non-physicians is feasible and should be considered for middle aged, moderate and heavy smokers experiencing breathlessness.

INTRODUCTION

The shift from secondary to primary care in Western countries coupled with falling medical manpower has increased the burden and stress on general practitioners (GPs) (Hodgkin, 1998). The refocusing of activities in primary health care towards, for example, the management of chronic diseases, has increased the workload in the primary care sector even more (Richards et al., 2000). With chronic obstructive pulmonary disease (COPD) as one of the leading causes of death and disability in Western countries (Siafakas et al., 1995) - with prevalence and mortality rates still rising - in conjunction with current levels and distribution of the workload in general practice related to this, consideration has been given to allocating some or part of this work to other care-providers, including non-physicians. Patients with COPD often seek treatment too late in the course of the disease and reliable evidence suggests underdiagnosis in the general population, with only 25% of cases being diagnosed (Siafakas et al., 1995).

Early detection and treatment of patients with COPD is important (Postma & Sluiter, 1989). Dompeling et al. (1992) concluded that early detection of patients at

risk can be performed easily and effectively by GPs by monitoring and making use of ventilatory function indices, while others have shown the predictive value of findings like decreased expiratory breath sounds, shortness of breath or wheezing (Van Schayck et al., 1991; Badgett et al., 1993; Den Otter et al., 1997; Den Otter et al., 1998; Nihlén et al., 1999). Some studies even suggest to diagnose airflow limitation by risk factors alone (Van Schayck et al. 1991; Badgett et al. 1993).

To detect COPD in general practice, spirometry can be used and, if necessary, allocated to non-physicians (Quanjer et al., 1993; Geijer et al., 1997). In spite of the heavy workload, this solution has not until now been included in daily practice (Richards et al., 2000). Recently, nurse practitioners have been introduced into primary health care, tasked with treating COPD.

In the Maastricht region, a pilot programme was launched in which nurse practitioners, supported by undergraduates, routinely performed early detection and provided treatment to patients with previously unknown airflow obstruction. The guidelines of Dutch GPs, which have been drawn up in accordance with recently published international guidelines (Geijer et al., 1997), were used as a point of reference around which the activities of the non-physicians were organised.

The research question dealt with by this study concerns the extent to which the support offered by undergraduates and nurse practitioners to GPs in the early detection of patients with COPD is effective. This was measured in terms of the number of patients identified with COPD as well as by assessing the credibility of offered early detection. Ideally, subsequent to the early detection performed by non-physicians, patients should undergo the same investigation by physicians. In order to minimise the burden on patients and physicians, and taking into account the restricted resources, it was decided to assess the credibility of early detection provided in an alternative way. It should be possible to differentiate patients with airflow obstruction or COPD from patients without, on the basis of known risk factors. Thus to enable comparison with predictors found in other studies, the results of the lung function measurement were taken as the starting point to assess the predictive value of symptoms and medical history in the identification of patients at risk from airflow obstruction or COPD.

METHODS

Recruitment of participants

Between September 1998 and July 1999 the programme was offered to patients in eight practices of 12 GPs. These GPs belong to a group of practices participating in a project in which nurse practitioners perform a central role in the care of patients with

COPD. Half of these practices are run by single GPs, half by two partners. Although the nurses were already otherwise active in these practices, their involvement in the detection of COPD represented a new undertaking.

The practice assistant asked patients, visiting the general practice for reasons not related to a respiratory disease and aged between 40 and 70 years, if they were former or current smokers. If so, the GP assessed exclusion criteria. Patients who were already receiving lung medication, with a known diagnosis of asthma, COPD or chronic bronchitis or suffering from important concomitant morbidity (severe cardio-problems, cor pulmonale, active malignancies), were excluded from the study. After having given informed consent, patients were scheduled for assessment of their respiratory function according to the guidelines of Dutch GPs on COPD and asthma in adults (Geijer et al., 1997). In this way a convenience sample was obtained.

Programme and study were approved by the ethical committee of the university hospital Maastricht.

Protocol

Patients were examined according to the protocol as illustrated in figure 1. The protocol was separated in a screening and a diagnostic part. Initial lung function testing was performed by four medical undergraduates, who had received full day training in a university lung function laboratory. Moreover, during the first day their testing was supervised by a respiratory nurse practitioner. The medical undergraduates recorded the forced expiratory volume in one second (FEV_1) and the ratio of FEV_1 to forced vital capacity (FVC) using spirometry (Vitalograph 2120; spirometer without the facility of printing a curve). Patients with an FEV_1 less than 50% of the predicted value were eliminated from the study and referred to a pulmonologist. If the FEV_1 of patients was less than 84% of the predicted value or when the FEV_1/FVC ratio (both as percentage of the predicted value) did not exceed 65%, airflow limitation was assumed. For these patients reversibility of the airflow limitation was assessed by measuring the FEV_1 15 minutes after inhalation of 500μg terbutaline. The FEV_1/FVC ratio is also referred to as Tiffenau index (Siafakas et al., 1995).

In accordance with the guidelines, asthma was diagnosed if the FEV_1 before and after using terbutaline differed by more than 9% (Geijer et al., 1997). On the basis of these findings, treatment was started by the GP. These measurements were only used for initial screening. In case of irreversible airflow limitation, COPD was suspected and patients were invited for further diagnostic testing by one of two experienced respiratory nurse practitioners. If irreversibility was confirmed, the FEV_1 of patients was measured (Microlab 3300; spirometer with the facility for printing a curve) after which they were given 30mg prednisone daily for 14 days. If the difference between the FEV_1 measured before the second reversibility test and after the steroid-test was

smaller than 9%, COPD was diagnosed. If this reversibility was 9% or more, asthma was diagnosed (Geijer et al., 1997). If patients were diagnosed as having COPD, nurse practitioners started treatment in accordance with the GP.

Both medical undergraduates and respiratory nurse practitioners performed lung function tests according to European Respiratory Society (ERS) guidelines (Quanjer et al., 1993).

Symptoms and medical history

After inclusion but before first assessment of airflow limitation, patients were interviewed by undergraduates if a) ever asthma, emphysema, chronic bronchitis or allergy had been diagnosed, b) if these diagnoses were present in family, c) if they suffered from asthma or bronchitis during childhood, and d) if they suffered from cough in the morning, production of sputum, and breathlessness during exercise. Based on the results of first lung function measurement the sample was divided in a group of patients with and a group of patients without airflow limitation. The predictive value of symptoms and medical history for airflow limitation was then assessed. The predictors of COPD were identified according to the same method, using the results of the diagnostic test to divide the sample.

Analyses

Variables measured at the start of the study were used as predictors of airflow limitation and COPD in a logistic regression analysis. These involve: age, sex, body mass index (BMI), pack years (number of packs of cigarettes smoked per day multiplied by the number of years the individual has smoked), former diagnosis of asthma, emphysema, chronic bronchitis or allergy; presence of these diseases in family of the patient; presence of asthma or bronchitis during childhood; and the symptoms morning cough, sputum production, and breathlessness during exercise. For this purpose all variables were dichotomised. For age, BMI and pack years the mean value of patients with airflow limitation of COPD was used as cut-off value (≤ mean value/> mean value). Differences in the prevalences of variables were tested with Pearson chi-square. The odds ratios (OR) with their 95% confidence intervals (CI) and the statistical significance were determined for all predictors both separately (univariate analysis) and in combination (multivariate analysis). The goodness-of-fit test according to Hosmer and Lemeshow was used (Hosmer & Lemeshow, 1989). The predictive power of the models was tested by Receiver Operator Characteristic (ROC) Curves (Van der Schouw et al., 1992). Finally, in a ROC-analysis, data from logistic regressions were evaluated at different cut-off values to determine the maximum sum of sensitivity and specificity as the optimum cut-off value and the positive and negative

predictive values. As significance level, $\alpha = .05$ (two tailed) was used. Data processing and analyses were conducted with SPSS (Windows Release 9.0).

RESULTS

Patients and basic characteristics

The sample included a total of 231 patients from the eight practices. The mean age of all patients is 53.5 years, about half (48.5%) were male. About 62% are current smokers with a mean number of 31.2 pack years. Furthermore the group showed on average normal FEV_1 (3015±82 mL) and FVC (4112±105 mL). Of 205 patients, complete data were available from lung function tests and interview.

Early detection of COPD

After the first lung function test, two patients were referred to a pulmonologist. Airflow limitation was assumed to be present in 44 patients (19.0%), while in 185 patients (80.0%) a normal lung function was measured. One patient with an FEV_1 as percentage of predicted value above 84% had a Tiffenau index below 0.65 and was also administered terbutaline.

After the first administration of terbutaline, the FEV_1 as percentage of predicted value of 38 patients was less than 84% and for two patients the difference in FEV_1 before and after using terbutaline was less than 9%. In five patients asthma was diagnosed and treatment was started by the GP.

The subsequent diagnostic test was performed on 40 patients (Figure 1). After repeated spirometry, 12 patients had an FEV_1 as percentage of predicted value of 84% or more. In 28 patients with an FEV_1 as percentage of predicted value below 84%, reversibility was tested. After the administration of terbutaline FEV_1 as percentage of predicted value increased over 84% in two patients.

All 26 patients whose irreversibility was assessed at two different measurements were invited to participate in the steroid test. One patient was unable to perform the steroid test because of too poor command of Dutch language, while two patients refused to undergo the test. Seventeen patients were diagnosed as having COPD and six as having asthma.

Diagnoses of airflow limitation and COPD by patient's history and symptoms

Of 43 patients with airflow limitation and of 162 patients without airflow limitation, data were available from lung function tests and interview. The odds ratios for all

Figure 1
Flow chart early detection of COPD.

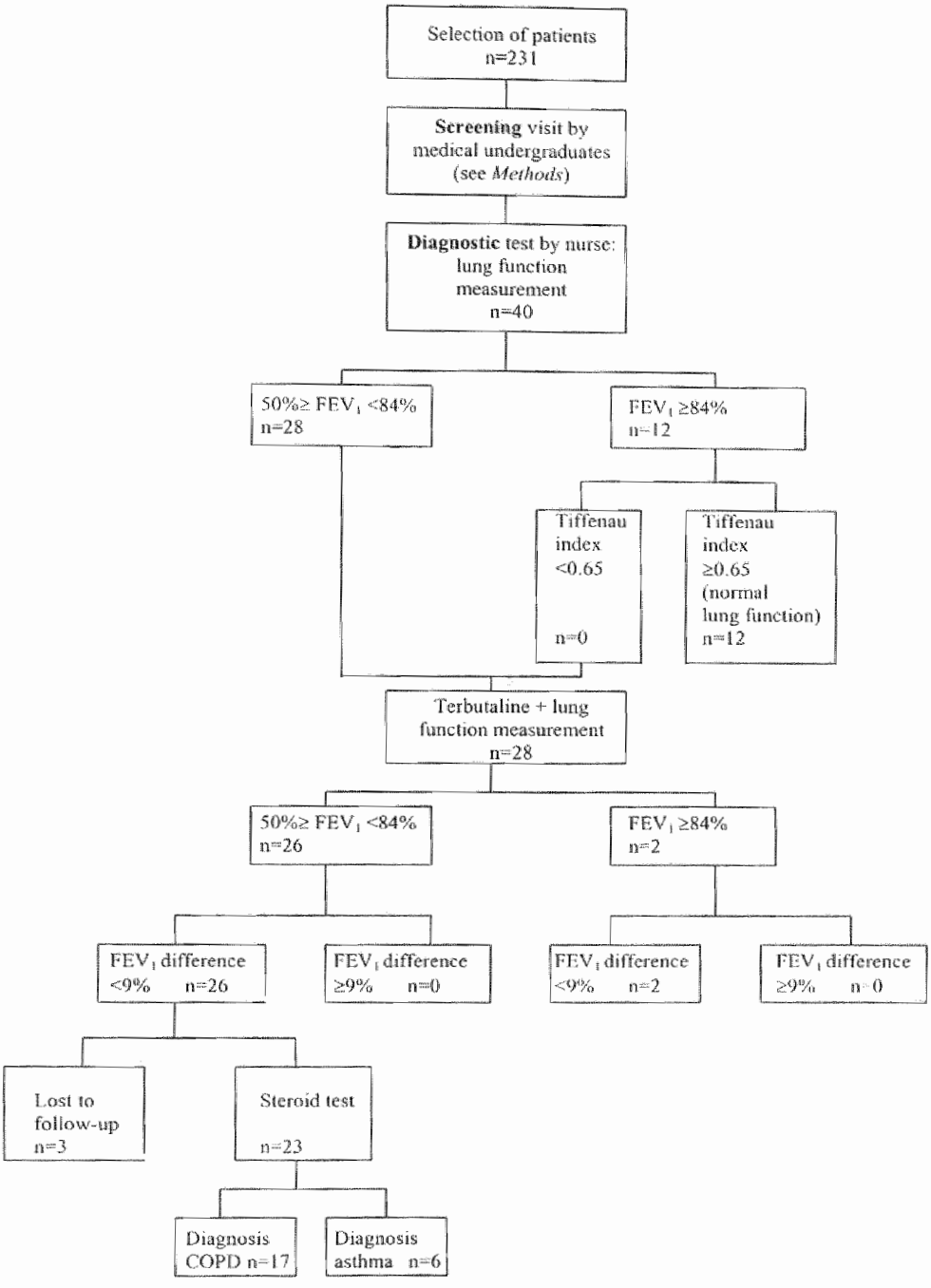

Table 1
Predictive value of potential risk factors for airflow limitation (N=43) and normal airflow (N=162)

Risk factor	Cut-off value	Prevalence normal[a]	Prevalence limitation[a]	univariate		multivariate	
				OR[b]	95% CI[c]	OR[b]	95% CI[c]
Age (yrs)	≥54.9	41	54	1.67	0.85–3.29	1.42	0.60–3.37
Sex	male	51	49	0.93	0.48–1.82	0.89	0.42–1.92
BMI (kg/m^2)	≥26.2	40	47	1.30	0.66–2.55	1.12	0.52–2.40
Pack years (yrs)	≥35.4	27**	49	2.64	1.32–5.28	2.41	1.02–5.68
Former diagnosis:							
asthma	yes	3	2	0.94	0.10–8.64	1.77	0.14–21.76
chronic bronchitis	yes	8	9	1.18	0.36–3.81	1.98	0.48–8.28
Morning cough	yes	25	37	1.81	0.88–3.69	0.95	0.30–3.00
Breathlessness	yes	36***	70	4.14	2.00–8.55	3.94	1.77–8.75
Sputum production	yes	22*	37	2.07	1.01–4.26	1.36	0.43–4.31
Allergic	yes	22	28	1.35	0.63–2.90	1.35	0.56–3.26
Asthma or chronic bronchitis during childhood	yes	14	5	0.31	0.07–1.38	0.21	0.04–1.09
Lung disease in family	yes	35	42	1.36	0.69–2.71	1.45	0.66–3.18

[a] tested with Pearson Chi-Square; [b] Odds Ratio; [c] 95% Confidence Interval; *p< .05; **p< .01; ***p< .001

potential risk factors for airflow limitation are presented in table 1. Because lung emphysema was not reported by patients this variable was left out of this analysis. Univariate analyses showed that pack years, breathlessness and sputum production were statistically significant predictors of airflow limitation with respectively 2.6, 4.1, and 2.0 times higher risk. In the multivariate logistic regression, breathlessness and pack years retained as risk factors for airflow limitation.

From the Hosmer and Lemeshow test it appeared that the model fits the data reasonably well (p=0.69). Furthermore, with an area under the ROC curve of 0.75, the model distinguishes between patients with airflow limitation and those without. The statistically optimum cut-off value, was found to be 0.29 or 0.30. Both values showed the highest sumscore (142%). Thus, when patients with a predictive probability of 0.29 or greater are classified as having COPD, 84% of patients with COPD according to lung function measurement are identified on the basis of the risk factor model and 58% of patients without COPD according to lung function measurement, are classified as patients without COPD on the basis of the model.

Because of the reclassification of 12 out of 40 patients after the first measurement by the nurse practitioner, we also looked for predictors of airflow limitation defined by the nurse. Statistically significant differences in prevalence were found for pack years and breathlessness. Both predictors of airflow limitation retained after univariate and multivariate analyses, with equal odds ratios. In addition the model now fitted the data reasonably well (Hosmer and Lemeshow test with p=0.76 and area under curve of 0.75), while the statistically optimum cut-off value was found to be 0.19 (sumscore=145%).

Of 16 patients with COPD and of 189 patients without COPD data were available from lung function tests and interview. The findings of the analyses of the predictive values of potential risk factors for COPD are presented in table 2. Male sex, pack years, breathlessness and sputum production were statistically significant predictors of COPD, of respectively 4.7, 6.8, 4.5, and 3.3 times higher risk. Because patients did not report the presence of asthma or emphysema, these two variables were kept out of the model. After multivariate analyses sex, pack years and breathlessness retained as statistically significant predictors of COPD. The Hosmer and Lemeshow test showed a p-value of 0.68, and the area under the ROC curve was 0.87. Like the airflow model the COPD model differentiates between observed and predicted values and discriminates between patients with and without COPD. The cut-off value of 0.08 was found to be the statistically optimum cut-off value (sensitivity=88%, specificity=80%, sumscore=168%).

Table 2
Predictive value of potential risk factors for COPD (N=16) and absence of COPD (N=189)

Risk factor	Cut-off value	Prevalence [a] without COPD	Prevalence [a] with COPD	univariate		multivariate	
				OR[b]	95% CI[c]	OR[b]	95% CI[c]
Age (yrs)	≥56.2	37	50	1.74	0.62–4.84	0.62	0.14–2.69
Sex	male	48**	81	4.77	1.32–17.27	4.27	1.04–17.42
BMI (kg/m^2)	≥25.8	46	50	1.17	0.42–3.25	0.80	0.24–2.75
Pack years (yrs)	≥38.4	24***	69	6.84	2.26–20.71	7.24	1.80–29.23
Former diagnosis:							
chronic bronchitis	yes	8	6	0.72	0.09–5.82	1.87	0.12–28.78
Morning cough	yes	26	44	2.22	0.79–6.28	0.78	0.12–5.31
Breathlessness	yes	40**	75	4.46	1.39–14.35	5.13	1.36–19.30
Sputum production	yes	23*	50	3.30	1.17–9.29	2.75	0.44–17.21
Allergic	yes	25	6	0.20	0.03–1.57	0.17	0.12–2.09
Asthma or chronic bronchitis during childhood	yes	12	6	0.48	0.06–3.82	0.67	0.06–8.09
Lung disease in family	yes	37	25	0.57	0.18–1.83	0.61	0.15–2.49

[a] tested with Pearson Chi-Square; [b] Odds Ratio; [c] 95% Confidence Interval; * p< .05; ** p<.01; *** p<.001

DISCUSSION

In this study the feasibility of a pilot programme based on current guidelines for Dutch GPs for early detection of COPD performed by non-physicians was assessed. Applying the programme to middle aged patients (n=231) at risk from COPD, who visited the GP for reasons not related to respiratory diseases, resulted in the identification of 17 patients with COPD (7.4%) and 11 patients with asthma (4.8%). Nihlén et al. (1999) reported a detection rate for COPD of 9.2% when corrected for known earlier diagnoses, which is fairly comparable with the rate found here. Nevertheless, selection bias might have occurred because of the nature of the sample.

Of the 40 patients with airflow limitation reported by the undergraduates, 12 patients (30%) were reclassified by the nurses. Inquiry revealed undergraduates experiencing difficulties with the instruction of patients to perform a good lung function test during the early stages of the programme. Adequate training can overcome this occurrence. In the setting of this study medical undergraduates were available, while it is imaginable that in a different setting practice assistants or practice nurses, if adequately trained, can perform lung function tests. Future research needs to be initiated here.

Furthermore, early detection of COPD with the support of undergraduates and nurses showed acceptable credibility. Without having the disposal of a golden standard, the predictive value of symptoms and medical history in identifying patients at risk from airflow obstruction or COPD was used as indication for the credibility of early detection. Logistic regression analyses showed the predictive value of pack years and breathlessness for both airflow limitation and COPD and also of sex for COPD. The predictive power of the models was acceptable. Positive and negative predictive values (not presented) as well as sensitivity and specificity of models also appeared to be acceptable at optimum cut-off values.

Other research reported smoking history, self-reported history of wheezing and wheezes during examination as best predictors of airflow limitation (Holleman et al., 1993), while diminished breath sounds (Den Otter et al., 1998), heavy smoking history (Den Otter et al., 1998), breathlessness and wheezing (Den Otter et al., 1997) were reported as best predictors of COPD. Physical signs have greater value in monitoring the severity of airflow limitation in COPD than in early detection (Badgett et al., 1993). In this study wheezing or physical signs as predictors of COPD were not studied. The finding that breathlessness and pack years are risk factors for COPD corresponds with earlier research. The increasing number of women who smoke, makes it likely that male sex as a risk factor for COPD will (continue to) decrease in the future. This is when sex category can be seen as risk factor, because sex probably just modifies the effect of pack years on COPD and therefore in itself is not a risk factor.

Future research should also be initiated to the complex interaction among predictors. In this study predictors were regarded individually and dichotomised or classified by using the mean value. Classification and Regression Trees (Breiman et al., 1984) can be used to study the interactions as well as find less arbitrary cut-off points for predictors.

How should a programme for early detection of COPD be organised? Firstly, detection of patients with early COPD should preferably take place in general practice (Van Schayck et al., 1991). Secondly, the services of non-physicians can be taken advantage of. Lung function measurement requires expertise that will be gained when performed routinely and can be carried out effectively by non-physicians. Nurse practitioners can also play a central role in the treatment of patients, which is subject of current evaluation. Ideally all listed patients of adult age in general practice should be screened, but if this is not feasible active case finding is recommended (Nihlén et al., 1999). Adult age, moderate or heavy smoking history and shortness of breath should be taken along when considering a more proactive strategy.

This study illustrates the development of the role of the nurse in primary care to one of partnership with the GP. By taking on roles and tasks traditionally performed by physicians shared decision making and mutual respect have become the new core values in care. Future research needs to address the effects of the allocation of work on patient outcomes, while issues like educational preparation for undertaking the new role, appropriate salary, and quality control also need to be addressed.

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8 CHAPTER

General discussion

INTRODUCTION

The main goal of this thesis was to obtain more insight into the effects on quality of care for patients with stable type 2 diabetes or COPD when tasks are transferred from physician to nurse specialist. In addition, in the phase of early detection of COPD the feasibility of the support provided by the nurse specialist to the GP was assessed, while for patients with RA low disease activity criteria, using the DAS28, were assessed for their feasibility to measure stability. It was assumed that the care-networks in which the nurse specialist performs a central role influence the outcomes of care.

The findings reported in the individual chapters are briefly summarised below. Subsequently, conclusions derived from the study findings about the role of the nurse specialist in the care for chronically ill persons are given. The methodological strengths and limitations of the research presented in this thesis are discussed, while this chapter ends with recommendations for further research and implications for health care professionals and policy makers.

SUMMARY OF FINDINGS

Chapter 2 examines whether the low disease activity criteria using the Disease Activity Score (DAS28) can be applied by nurse specialists to assess the degree of disease stability in patients with rheumatoid arthritis, and whether these criteria are sufficiently reliable to select stable patients out of an outpatient population for enrolment in a care-network. Compared to diabetes and COPD, for RA there is no internationally accepted parameter to assess stability. Patients regularly seen at the rheumatology outpatient department of the University Hospital Maastricht were invited for assessment of the stability of their rheumatoid arthritis. Sixty-six (66) patients completed the study – completion rate of 68% – and underwent three assessments using the DAS28. With almost 40% of patients classified as stable and a good similarity score, the low disease activity criteria using the DAS28 criteria were found to be applicable for the selection of patients with stable, low disease activity of rheumatoid arthritis out of a rheumatology outpatient department.

Chapter 3 presents a review of the literature, focusing on a selection of ten trials concerning the effectiveness and efficiency of models of care for patients with type 2 diabetes or COPD where the nurse has a central role. The trials showed differences in the roles or tasks performed by the nurse and therefore in the outcomes assessed and realised. Survival, clinical parameters, quality of life, self-care, and patient satisfaction are regarded as indicators for effectiveness, and these are related to medical consumption and costs for the assessment of efficiency of the models of chronic care. Furthermore, it was found that clinical parameters did not improve as often as expected.

Moreover, improvements in quality of life, self-care, and patient satisfaction occurred, while patients had higher medical consumption when they were cared for by the nurse specialist. The review indicated that, depending on the content of the intervention, effective and efficient models of chronic care with the nurse in a central role had been devised. It was noticed that evaluative studies about both the processes and effects of care are needed to gain more insight into how high quality care should be maintained in the near future.

To enable the reader to compare the main characteristics and findings of the central research questions, presented in chapters 4, 5 and 6, with the way the literature was reviewed in chapter 3, these are summarised in Tables 1 and 2.

Chapters 4 and 5 present the findings of two care-networks for patients with type 2 diabetes with the nurse specialist in a central role (Table 1). Chapter 4 investigates the effects on quality of care, when care for patients with stable type 2 diabetes is transferred from outpatient department to general practice and from endocrinologist to nurse specialist – diagonal substitution. The nurse specialist, having the highest level of qualification and specialised in diabetes, performed tasks concerning direct patient care, organisation and co-ordination of care for individual patients, consultation, and advancement of expertise. The first three of the recommended quarterly consultations during one year were transferred to the nurse specialist, leaving one consultation for the endocrinologist. The intervention was carefully described in a protocol and agreed by all parties involved. Using a 12-month non-equivalent control group design, it was found that except for glycaemic control, groups were comparable for health status, self-care behaviour, knowledge of diabetes, patient satisfaction, and consultations with main care-providers (Table 2). The mean HbA_{1c} level for outpatients cared for by the nurse specialist in the primary care setting improved (with -0.3% to 8.3%; n=31), while the mean HbA_{1c} level for patients cared for by the endocrinologist in the outpatient setting showed a statistically significant deterioration (with +0.2% to 8.8%; n=23, p-value between groups = 0.001).

Applying a 12-month one-group pretest-posttest design with additional comparisons using data from the study in the chapter 4, the transfer of care for patients with stable type 2 diabetes from general practitioner to nurse specialist – vertical substitution – was studied in chapter 5. With a few minor adjustments, use was made of the protocol formulated in chapter 4. For instance, the number of consultations performed by the nurse was not fixed, while the annual consultation by the general practitioner was. Again statistically significant improvements in glycaemic control were found (with -0.3% to 7.7%; n=158), as were improvements in health status, self-care behaviour, knowledge of diabetes, and patient satisfaction. Patients reported a statistically significant increase in the number of consultations with main care-providers. Chapters 4 and 5 show that substitution-based care-networks, with the nurse taking on roles and tasks traditionally performed by the physician, result, in

Table 1
Main characteristics of studies presented in chapters 4, 5, and 6

Chapter	disease	study design	type of care		number of patients		RR[c] / CR[d]
			IG[a]	RG[b]	IG	RG	
4	diabetes type 2	non- equivalent control group	usual care by nurse specialist to outpatients in primary care setting	usual care by endocrinologist to patients in outpatient department	52[e]	47	64 / 55
5	diabetes type 2	pretest- posttest [with additional comparisons]	usual care by nurse specialist to patients in primary care setting	[usual care by endocrinologist to patients in outpatient department]	175 [44[e]]	[47]	54 / 59 [55 / 47]
6	COPD	randomised controlled trial	usual care by nurse specialist to patients in outpatient department	usual care by pulmonologist to patients in outpatient department	91	83	93 / 85

[a]IG = intervention group; [b]RG = reference group; [c]RR = response rate; [d]CR = completion rate; [e]intervention *sub*group without the patients receiving oral hypoglycaemic agents and/or diet only

Table 2
Statistically significant outcomes of studies presented in chapters 4, 5, and 6

Chapter	disease	clinical outcomes	quality of life	self-care/ knowledge	patient satisfaction	total medical consumption
4	diabetes type 2	+	=	= / =	=	=
5	diabetes type 2	+ [=]	= [=]	+ / + [= / =]	= [=]	* [=]
6	COPD	=	=	+ / +	+	*[a]

+ statistically significant improvement; *statistically significant increase; = equivalent outcome; [ ] additional comparisons; [a] based on the registrations by care-providers, no difference was reported by patients

terms of patient outcomes, in equal quality of care with improvements in glycaemic control.

In chapters 6 and 7 interventions with the nurse specialist in a central role in the care for patients with COPD were studied. The effects on quality of care when tasks are transferred from pulmonologist to nurse specialist in the care for outpatients with stable COPD – vertical substitution – were studied in Chapter 6. Care was provided by the nurse specialist, having the highest level of qualification and specialised in COPD, working under a protocol in the outpatient department of a hospital. Using a nine-month randomised controlled trial, it was found that groups (intervention group n=91, control group n=83) were fairly equal for clinical parameters, health status, knowledge of COPD, and self-care behaviour, while patients cared for by the nurse specialist received statistically significantly more consultations and reported statistically significantly higher satisfaction with care. It was concluded that the transfer of care for outpatients with stable COPD with the nurse working under a protocol is, in terms of patient outcomes, a justifiable alternative for care delivered by the pulmonologist. Patients, visiting their general practitioner for reasons not related to a respiratory disease, who stated they were former or current smokers had their respiratory function assessed by the nurse specialist in the primary care setting, as reported in Chapter 7. COPD was detected in 7.4% of patients at risk (n=231), while the credibility of the early detection by non-physicians in general practice was confirmed by strong predictive values of pack years and breathlessness in these patients. It was concluded that the services of the nurse specialist are also useful for the early detection of COPD.

CONCLUSIONS

There are both intrinsic and extrinsic rationales for placing the nurse specialist in a central role in the care for patients with chronic diseases. Against the background of the growing number of chronically ill people and their unique needs, the reallocation of work according to skills and experience of caregivers and the combination of care with cure has resulted in a new pro-active approach to chronic care with a central role for the nurse specialist. Extrinsic motives are the high workload of physicians and a predicted shortage in their numbers in the near future. Considering the existing arrangements for the delivery of care, it is believed that the nurse specialist can substitute for the physician in the care for patients with a chronic disease in a stable phase as part of an interactive and interdependent network of care delivery.

The review of the literature revealed a paucity of (randomised) controlled trials investigating the effects of the nurse specialist substituting for the physician on quality of care for chronically ill patients. However, from the selected publications it was

found that giving the nurse specialist a central role in the care for patients with type 2 diabetes or COPD is justified in terms of patient outcomes. Using three different study designs in various settings for patients with stable type 2 diabetes or COPD, it was found that in terms of effects on patient outcomes the transfer of care from physician to nurse specialist is justified; at least equal outcomes were established. Furthermore, it is concluded that also in the phase of early detection of COPD, nurse specialists can play an important role by independently performing lung function measurements and diagnosing patients. Finally, for RA it was found that, applying the low disease activity criteria based on the DAS28, a substantial proportion of outpatients can be identified as having 'stable' RA. This finding suggests that, like diabetes type 2 and COPD, RA is a relevant and suitable chronic disease to unfold an inter-professional network of care delivery.

METHODOLOGICAL CONSIDERATIONS

Research design

Performing research into the effects of an intervention on the quality of care assumes the presence of some model of cause and effect, while assessing effects on the aspect of outcomes of quality brings one directly to quantitative methods of research. However, considering the delivery of health care as an open system, the possibilities of multiple causation and contingent causes create problems in its evaluation (Cook & Campbell, 1979). In a recently published review, the methodological value of comparative analyses of the individual practice of physicians, nurses, and midwives of evaluations has been questioned (Watts et al., 2001). Because of the occurrence of methodological constraints when evaluating complex, composite interventions in daily practice of health care delivery, Van Weel and Knottnerus (1999) conclude that the randomised controlled trial is very difficult to apply. With the care-network being refined and adjusted in daily practice, standardisation of the intervention is impossible. Desirable elements of methodology for scientific research, like a control group, randomisation, and blinding, are also difficult if not impossible to realise (Steuten et al, submitted). While this might, coupled to the early stage of this field, explain the paucity of (randomised) controlled trials about the effectiveness of the nurse substituting for the physician, the adoption of (potential) effective interventions in the delivery of health care is strongly guided by evidence derived from traditional, quantitative research.

In the studies published in this thesis, concepts of traditional, quantitative research were used to the level permitted by the individual settings to provide insight, together with the forthcoming findings of the process evaluation, into the effects on quality of care. The application of the low disease activity criteria, as presented in chapter 2, is a

pragmatic solution in order to evaluate, in a clinical situation, the suitability of RA as a chronic disease where the nurse specialist might play a role in the delivery of care to a selected group of patients. The DAS28 has not been developed for assessing stability of RA of patients.

Unconventional methods were used in the study presented in chapter 7, where the level of confidence of the early detection of COPD by the nurse specialist was compared with the risk profile of patients. Constraints of the burden on patients and physicians, when using a subsequent assessment by the physician, meant that only known risk factors could be applied as the standard for the credibility of early detection by nurse specialists.

In evaluating the effects on quality of care for patients with stable type 2 diabetes (chapters 4 and 5) or with stable COPD (chapter 6) when the nurse specialist is given a central role in the delivery of care, three different designs were used. Acknowledging the circumstances encountered, use was made of a non-equivalent control group design (chapter 4), a pretest-posttest design with additional comparisons (chapter 5), and a randomised controlled trial (chapter 6). From the findings of these three studies, it was concluded that the nurse specialist can substitute for the physician in the care for patients with stable diabetes type 2 or COPD.

Is a quasi-experimental or observational design then sufficient to evaluate the effectiveness of different models for the delivery of care? To answer this question, other main factors influencing the methodological quality of findings are discussed. These factors are interventions, outcome measures, populations (external validity), and statistical analyses (together with design: internal validity) (CRD, 2001).

Standardisation of care

For all interventions reported in chapters 2, 4, 5, 6, and 7 protocols were formulated to standardise the care provided by the nurse specialist. For the studies in chapters 4, 5, and 6 this meant that the complete phase of care delivery was defined in the protocol. For the number of consultations of patients with main care-providers, as administered by patients, a possible bias occurred in the observational study (chapter 5). In this study it seems that patients consulted both the nurse specialist and the general practitioner for their diabetes. As discussed in chapter 5, this increased consumption was not reflected in a difference in direct medical costs. Blinding of study-participants was impossible. Findings derived from the process evaluation will shed more light on the occurrence of performance bias. As for the stability of the intervention, a learning effect from the nurse specialist might occur.

For the assessment of stability of RA in patients (chapter 2), it is very unlikely that potential changes in care, as provided by the rheumatologists, were reflected in the assessments performed within a period of six months. Performance bias with regard to

the early detection of COPD, thus the performance of a lung function assessment, did occur. Patients with airflow limitation as reported by the undergraduates were reclassified by the nurses. This was due to difficulties with the instruction of patients to perform a good lung function test during the early stages of the programme. While this only results in false positive findings, a better training programme can overcome this occurrence.

Outcome variables and instruments

The set of outcomes used in the studies presented in chapters 4, 5, and 6 was based on accepted objectives in the care for chronically ill people and covers all relevant outcomes (Driessen et al., 1994). Internationally accepted clinical outcomes were assessed for diabetes type 2 and COPD. When comparing the presence of data from clinical parameters between groups, it was seen that for patients cared for by the nurse specialist data are more complete than for patients cared for by the physician, a finding made clear by the experimental designs (chapters 4 and 6). Firstly, this indicates that the nurse specialist works more closely to the protocol. With respect to the quality of the care delivery it is unclear what this difference exactly means. From chapter 6 it was found that pulmonologists provide fewer consultations to patients in a relatively more stable phase of COPD. Although this might suggest that nurse specialists are stronger initiators in care, without evidence about the optimal frequency of consultations for chronically ill patients this remains controversial. Secondly, this might indicate that patients cared for by the nurse specialist have more consultations than patients receiving usual care. Although this is confirmed by the results from the experimental studies (chapters 4 and 6), the numbers of consultations with the nurse specialist were in accordance with the protocol. The differing presence of clinical outcomes did not prevent performing analyses, but did influence the applicability of statistical analyses. Repeated measures analyses were performed in chapter 4, while in chapters 6 independent sample t-tests were performed.

For the measurement of quality of life, the Visual Analogue Scale (Maxwell, 1978) and COOP/WONCA charts were chosen to enable more general conclusions to be drawn (Nelson et al., 1987). It should be emphasised that no direct effect from the nurse specialist on quality of life was expected, but rather an indirect effect with clinical outcomes, knowledge and/or self-care as intermediate factors, was regarded as possible. The Visual Analogue Scale was replaced by a disease-specific instrument in the study for patients with COPD for two reasons (chapter 6). Firstly, whilst showing better glycaemic control but no change in quality of life, the generic instruments to measure quality of life might not be sensitive enough to measure a possible change. The second reason was that quality of life as outcome parameter has a more specific meaning in the treatment of COPD and thus requires a disease-specific instrument.

For patients with COPD, the COOP/WONCA charts and the St George's Respiratory Questionnaire (Jones et al., 1992) were used. Without finding differences for quality of life within or between groups, as measured with generic and specific instruments, the conclusion that with the nurse specialist as main care-provider equality in quality of life is achieved, seems to be rather robust. Measuring quality of life over a longer period of time should be undertaken to shed more light on this topic.

Self-care behaviour and disease-specific knowledge of patients are important outcomes when redesigning care-delivery towards a model in which the patient has more responsibility. Both outcomes were measured with disease-specific instruments developed in the Netherlands (Deenen, 1996; Pennings-van der Eerden, 1992; Ripken et al., 1990). Among all outcomes, lowest completion rates were scored for these instruments, which might be translated as the instruments being too difficult for some patients to complete, or as too confrontational for some patients. Higher response rates might be achieved when the assessment of self-care behaviour and knowledge are assessed during consultation, offering the additional possibility for care-providers to make instant use of this information. The instruments should be evaluated for this function. Notwithstanding the imperfect completion rates, indications exist that the nurse specialist improves the level of self-care behaviour and knowledge of patients, after being introduced as the main care-provider (chapters 5 and 6). In chapter 4 the nurse specialist, although not as main care-provider, was already active on this area before the start of the study – as reflected in high scores at baseline – which might explain the absence of further improvements in the setting in question.

Patient satisfaction was assessed by instruments derived from industrial marketing management, which have been applied in the same area of research before (Cockroft et al., 1987; GRASSIC, 1994; Littlejohns et al., 1991; Sum et al., 2000). These instruments also served as the basis for a recently developed instrument for satisfaction with health care delivery (Wensing, 1997). Using the 'marketing-instruments' made clear that the care-network with the nurse specialist in the central role is well accepted by patients (chapters 4, 5, and 6). Only when patients are asked to grade their satisfaction for specific aspects of care-delivery, is it possible to make an inventory of the aspects in need for improvement. From chapter 6, it was clearly seen that higher proportions of patients cared for by the nurse were satisfied with care received than of patients receiving usual care. In other words, the room for improvement in usual care is bigger than in the care with the nurse specialist in the central role. A finding confirmed by the results of a focus group interview under patients with diabetes type 2 or COPD in the region of Maastricht (Koppers, 2000). While a relationship between length of consultation and patient satisfaction exists, in another study it has been found that differences remained statistically significant when this was accounted for (Sum et al., 2000).

Consultations with main care-providers were measured by means of a self-developed booklet in the studies presented in chapters 4 and 5, while in chapter 6 the regis-

trations of care-providers were also used as data-source. With respect to the booklets, it was found that not all patients filled in the booklets for the intended time period when compared with the data derived from the registrations of care-providers (chapter 6). However, when considering the data for the entire study-period, it is unlikely that this inaccuracy has resulted in invalid conclusions. Similar consideration applies to the other data gathered by questionnaire, although for these outcomes a possible inaccuracy is of less significance. Again, combining consultations with the collection of data might be a solution for this bias.

One variable of highly relevance was not measured in the studies presented in this thesis. With the focus on the aspect of effectiveness, outcomes were not related to their inputs. Considering the limited resources of this effect evaluation, it was decided to evaluate the effectiveness first. However, the question 'how efficient is the care-network?' has even become more relevant and should be addressed in the near future.

In chapter 2 the low disease activity criteria using the DAS28 were applied to assess stability in patients with RA, while these criteria have not been developed for this purpose. Without the existence of a gold standard to assess stability in RA, the findings cannot always be interpreted unambiguously but nevertheless they yielded conclusions in which one can have confidence. Moreover, in the absence of a gold standard, the credibility of early detection of COPD by the nurse specialist was assessed by making use of known risk factors (chapter 7). By combining the lung function measurement and the gathering of data on risk factors of patients, this strategy proved to be acceptable.

Power considerations and populations

No power calculation was performed for the quasi-experimental study presented in chapter 4. Here, as in the study presented in chapter 5, the sample size was defined by the local circumstances, i.e. the number of participating general practitioners, the criteria for stability, and the willingness of patients to participate. For the randomised controlled trial (chapter 6) a power calculation was performed, taking patient satisfaction as primary outcome. Moreover, based on the GRASSIC study (1994), it was calculated that, to find a difference in satisfaction rate of 0.7 on a scale between 1 and 10, a number of 75 patients per group was needed.

Allocation of patients to groups took place on level of participation of general practitioners in the study presented in chapter 4, while patients were allocated at random in chapter 6. Differences between comparison groups at baseline were found in chapter 4. With no patients in the control group being treated by oral hypoglycaemic agents alone, analyses were performed between patients receiving oral hypoglycaemic agents and/or insulin. If this affected the study results, then it would certainly not be

advantageous for the nurse specialist. With only modest response rates and completion rates in the studies with type 2 patients, the drop-out of patients is even more precarious with poorer controlled people not finishing the studies. As discussed in chapters 4 and 5, this might have influenced the results, but did not affect the conclusions. A possible explanation for the relatively high response rate and completion rate in the study for patients with stable COPD (chapter 6) might be the non-academic setting with patients not being tired of the umpteenth scientific research.

The loss of one third of the group of patients with RA (chapter 2) also needs attention. It was conceivable that the patients with missing data had more often non-stable RA. Moreover, if data had been available for these non-stable patients, the test-retest reliability of the low disease activity criteria using the DAS28 would have been smaller. However, it is unlikely that the missing data would have affected the proportion of patients with stable RA. Also in the study about the early detection of COPD, a small number of patients (n=26) dropped out (chapter 7). Apart from the possible influence on the study findings, for these patients there is a danger that, in case of airflow limitation, treatment will start too late and thus is less effective.

Statistical analyses

Incongruence in the unit of allocation and the unit of analysis occurs in much experimental research about the effectiveness of interventions aimed at improving the quality of diabetes care (Renders, 2001). Moreover, this unit of analysis error increases the apparent precision of estimates (Divine et al., 1992). When the intervention is directed at care-providers, but the outcomes are analysed at the patient level, ideally the clustering of patients within care-providers should be taken into account. The observations made of patients cared for by the same provider are not independent. Standard methods of analysis that ignore the clustering of patients within providers affect the study findings and might even result in incorrect conclusions (Renders, 2001).

For the experimental study reported in chapter 4 this error did occur. In this study patients received diabetes care from one of two nurse specialists, when their general practitioner was willing to participate in the care-network; otherwise patients received usual care by one of five medical specialists. In chapter 6 patients were allocated to the nurse specialist or the pulmonologist, while outcomes were analysed on the patient level.

To protect against systematic differences between comparison groups in terms of non-respondents, intention to treat analysis was applied. Especially for pragmatic trials of effectiveness, intention to treat analysis is suitable (Roland & Torgerson, 1998). According to a recently suggested method for the handling of missing responses (Holis & Campbell, 1999), intention to treat analysis was applied by using

the last observed response (chapters 4 and 6). Based on the primary findings in chapter 5, it was assumed that unchanged outcomes on the group level could be imputed in terms of the means of outcomes for individuals.

In conclusion, experimental designs are difficult to apply in these settings but, because of the difficulties encountered, offer more insight into the effectiveness of the intervention than observational studies, when conducted appropriately. Experimental designs are preferable, but should not have exclusivity in this area of research because absence of evidence – which should not be confused with evidence of absence (Altman & Bland, 1995) – should be avoided.

RECOMMENDATIONS

As recently stated in the Netherlands as well as in other industrialised countries and confirmed in chapter 3, evidence of the effectiveness of nurse specialists is at present unclear (Laurant et al., 2002; Loveman et al., 2002; Richardson et al., 1998; Temmink, 2000; Van der Linden, 2001). The studies presented in this thesis contribute to a better understanding of the effects of substituting nurse specialists for physicians. The extent to which this thesis will help policy makers and health care professionals to achieve good quality care is outlined below. Finally, topics for further research are identified.

Recommendation for policy

From the findings presented in this thesis, it is concluded that the central role in the care for patients with stable diabetes type 2 or COPD for the nurse specialist is justified. To make full advantage of the services of the nurse specialist, this profession needs to be institutionalised and legalised. Therefore it should become clear how the role, skills, and responsibilities of the nurse specialist relate to the medical professions as well as to the other non-physician practitioners. Currently, a number of non-physician practitioners are claiming, mostly without a strong evidence base, a role in the delivery of care to chronically ill people. Aspects of controversy and conflict should be prevented, as these are only harmful for the patient. Professional and occupational boundary redefinition should take place.

An important element of this redefinition is the education required to fulfil a particular role in care-delivery. In the Netherlands, only since April 2001 has an accredited course been launched for nurses willing and able to specialise in diabetes mellitus, while for specialities like COPD or RA still no officially recognised courses exist. For non-physician practitioners other than the nurse specialist, no accredited educational programmes exist either. Although 'learn by doing' and ultimately being

able to provide justified care has worked so far, it is undesirable for wise and wide implementation. In the construction of these educational programmes the current single-professional approach has to be changed in an inter-professional focus.

The change in tasks and activities as well as the related responsibilities should be converted in the salary of care-providers and in the price of the product delivered. This price should represent the true costs of the product and should not be an administrative price. The new pricing system being developed now, called 'Diagnose Behandel Combinaties' (in English: diagnosis treatment combinations), might accommodate this. One should not be surprised if ultimately more resources will be needed, or in the words of Donabedian (1986), 'it should be clear to everyone, though sometimes we seem to forget it, that more quality must cost more.'

In the interventions evaluated, supervision of the nurse specialist by the medical specialist was given, while the nurse specialist functioned as a consultant towards general practitioners and simultaneously offered general practitioners better access to the medical specialist. Substitution was thus accompanied by collaboration across different levels of care delivery. The structure of the care-network requires shared responsibility, good communication, successful co-ordination, and democratic relationships between care-providers. Sharing responsibilities implies that the nurse specialist gains more autonomy in care as compared to the traditional situation. Legislation needs to reflect practice in which the nurse specialist performs tasks that belonged to the domain of the physician, including shared responsibility. As an illustration of the uncomfortable current situation, if the nurse specialist, based on the findings from the consultation with the patient, wants to refer to the dietician, authorisation from the physician is required. The latter, however, is generally only involved in giving his/her signature. Legalised authority for nurses to make certain referrals without asking for the physician's signature is needed. Moreover, when applying a team approach, it seems reasonable to hold different care-providers responsible for the care provided by them. For patients, it should be clear who is ultimately responsible for the delivery of care. For the Netherlands this would require amendments to the Individual Health Care Professionals Act (Wet Beroepen Individuele Gezondheidszorg) and to the Medical Treatment Act (Wet Geneeskundige Behandelings Overeenkomst).

To facilitate or enhance interdisciplinary communication, relationships, and teamwork, it will be necessary to both recognise the potential danger for participants, as well as the potential gains. Professional co-ordination is indispensable to facilitate the necessary conditions, leaving care-providers and patients in the primary process and responsibility with the care-providers. Furthermore, professional co-ordination should play an important role in quality control and improvement of the delivery of care. Suitable tools like protocols, information technology, electronic patient records, benchmarking and feedback exist, but need to be developed for or tuned to the inte-

grated care setting and be successfully implemented in daily practice. Without care-providers adopting a transparent and accountable work-environment, quality control and improvement are not feasible.

For wider implementation of the nurse specialist in a central role in the care for patients with a chronic disease, the capacity of the nursing workforce has to increase. In this context, policy makers need to address the following issues: the availability of nurse specialists for substitution, the desirability and possibility of a movement up the nursing skills spectrum of the other nurses, and the optimal nurse-physician ratio. Although complex, these issues need to be explored to be able to plan the workforce on both national and local level.

With respect to the suitability of diseases for which an inter-profession model of care delivery can be applied, RA, like diabetes type 2 and COPD, can be managed appropriately. Moreover, with almost 40% of outpatients assessed as having stable RA, compared with the percentage of outpatients with stable COPD – 26% of the population studied in Alkmaar (chapter 6) – RA seems to offer even higher potential for disease management with the nurse in a central role. Other diseases like heart disease, HIV/AIDS, cancer and depression are also believed to be suitable and relevant for redesigning the care delivery in a more comprehensive way. For the management of these diseases too, (more) scientific research is needed.

Recommendation for further research

Several recommendations for further research have already been mentioned in the individual chapters of this thesis. The most compelling of these as well as some broader recommendations are mentioned here.

The choice for the research designs applied in the studies presented in this thesis was defined by the local circumstances where the intervention was implemented. More empirical evidence is needed on the merits of various designs in this area of research. To evaluate the consequences of substitution for professions or factors determining the adoption of new roles, both quantitative and qualitative research should be applied to provide complementary information. Moreover, iterative research should be performed.

With regard to the assessment of patient outcomes in people with a chronic disease, preferably longitudinal data have to be gathered. When evaluating structural concepts of chronic care delivery, in addition to disease specific instruments, generic and standardised instruments have to be applied to enable conclusions to be drawn that are broader than individual chronic diseases. With regard to the measurement of disease-specific knowledge and self-care behaviour of patients with a chronic disease, internationally applicable and valid instruments need to be developed. Moreover, the feasibility of these instruments in daily care-delivery needs to be established. Research

is needed to identify the factors leading to differences in patient satisfaction. The influences of the several outcomes on each other have to be established.

Research should be initiated into the establishment of the optimal number of consultations for patients with a stable chronic disease. Research should also be initiated to establish the optimal nurse-physician ratio. A related topic is the standardised evaluation of the cost-effectiveness of models in which the nurse specialist has the central role. This implies that consensus has to be reached on the methodological requirements of cost-effectiveness research or Health Technology Assessment of multifaceted interventions.

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SAMENVATTING

Het hoofddoel van dit onderzoek was het verkrijgen van inzicht in effecten op kwaliteit van de zorg voor patiënten met stabiele diabetes type 2 of stabiele chronische luchtwegobstructie (COPD), wanneer die zorg wordt verschoven van arts naar verpleegkundig specialist. Daarnaast is de haalbaarheid van ondersteuning van de huisarts door de verpleegkundig specialist in de fase van vroege opsporing van COPD onderzocht, terwijl de Disease Activity Score (DAS28) is onderzocht op zijn geschiktheid om stabiliteit van reumatoïde artritis (RA) bij patiënten vast te stellen. Verondersteld werd dat de uitkomsten van zorg zouden worden beïnvloed door de centrale positie van de verpleegkundig specialist in de diverse zorgnetwerken. Substitutie van zorg en transmurale zorg worden namelijk beschouwd als manieren om de samenwerking en de afstemming in de zorg voor chronisch zieken te verbeteren alsmede de effectiviteit en efficiency van deze zorg.

In hoofdstuk 2 wordt onderzocht of de DAS28 geschikt is om de mate van stabiliteit van RA door verpleegkundig specialisten vast te stellen en of de hierop gebaseerde criteria voldoende betrouwbaar zijn om patiënten in een stabiele ziektefase uit een polikliniche patiëntengroep te selecteren ter includering in een zorgnetwerk. In vergelijking met diabetes en COPD is er voor RA geen internationaal geaccepteerde parameter om stabiliteit vast te stellen. Patiënten die met regelmaat op de polikliniek reumatologie van het academisch ziekenhuis Maastricht komen, werden uitgenodigd voor het vaststellen van de mate van stabiliteit van hun RA. Zesenzestig (66) patiënten deden mee aan het onderzoek (completion rate 68%) en ondergingen drie metingen met de DAS28-criteria. Met bijna 40% van de patiënten geclassificeerd als stabiel en een goede overeenstemmingsscore, blijkt dat de DAS28-criteria geschikt zijn om patiënten met stabiele, laag actieve RA te selecteren uit een poliklinische patiëntengroep met RA.

Hoofdstuk 3 beschrijft de resultaten van een literatuurstudie met tien trials in termen van de effectiviteit en de efficiency van zorgmodellen voor patiënten met diabetes type 2 of COPD waarin de verpleegkundige een centrale rol bezit. De trials laten verschillen zien in de rollen en de taken die de verpleegkundigen uitvoeren en daarmee in zowel de onderzochte als geconstateerde effecten. Overleving, klinische parameters, kwaliteit van leven, zelfzorggedrag, en patiënttevredenheid worden beschouwd als indicatoren voor effectiviteit, en worden gerelateerd aan medische consumptie en kosten ter bepaling van de efficiency van de modellen voor chronische zorg. De literatuurstudie laat zien dat klinische parameters niet zo vaak verbeteren als verwacht wordt. Verbeteringen in kwaliteit van leven, zelfzorggedrag en patiënttevredenheid treden op, terwijl patiënten een hogere medische consumptie rapporteren wanneer ze zorg krijgen van de verpleegkundig specialist. Verder blijkt uit de literatuurstudie dat, afhankelijk van de samenstelling van de interventie, effectieve en efficiënte modellen voor chronische zorg met een centrale rol voor de verpleegkundige zijn uitgewerkt. Geconstateerd wordt dat evaluatieonderzoek naar de processen en de

effecten van de zorg voor chronisch zieken nodig zijn om meer inzicht te krijgen op welke wijze goede kwaliteit van zorg kan worden gehandhaafd in de nabije toekomst.

Om de lezer in staat te stellen de belangrijkste eigenschappen en resultaten ten aanzien van de centrale onderzoeksvragen, zoals die zijn gepresenteerd in hoofdstuk 4, 5 en 6, te vergelijken met de samengevatte literatuur in hoofdstuk 3, zijn deze samengevat in tabel 1 en tabel 2.

Hoofdstuk 4 en 5 laten de resultaten zien van twee zorgnetwerken voor patiënten met diabetes type 2 waarin een centrale rol wordt vervuld door de verpleegkundig specialist (tabel 1). Hoofdstuk 4 onderzoekt de effecten op kwaliteit van zorg als zorg voor patiënten met stabiele diabetes type 2 wordt verschoven van polikliniek naar huisartsenpraktijk èn van endocrinoloog naar verpleegkundig specialist (diagonale substitutie). De verpleegkundig specialist, welke het hoogste verpleegkundig kwalificatieniveau heeft en gespecialiseerd is in diabetes, voert taken uit betreffende de directe patiëntenzorg, de organisatie en de coördinatie van zorg aan individuele patiënten, consultatie en de bevordering van expertise. Drie van de aanbevolen driemaandelijkse consulten worden verschoven naar de verpleegkundig specialist, terwijl één jaarlijks consult aan de endocrinoloog blijft voorbehouden. De interventie is zorgvuldig protocollair vastgelegd en ontving instemming van alle betrokken partijen. Op basis van een non-equivalent control group design blijkt na 12 maanden dat, met uitzondering van de glycaemische controle, patiëntgroepen vergelijkbaar zijn qua gezondheidstoestand, zelfzorggedrag, kennis over diabetes, patiënttevredenheid, en consultaties met zorgverleners (tabel 2). Het gemiddelde HbA_{1c} niveau van patiënten die zorg ontvangen van de verpleegkundig specialist in de huisartsenpraktijk verbetert (met–0.3% tot 8.3%; n=31), terwijl het gemiddelde HbA_{1c} niveau van patiënten die zorg ontvangen van de endocrinoloog op de polikliniek verslechtert (met +0.2% tot 8.8%; n=23, p-waarde tussen groepen=0.001).

Door gebruik te maken van een one-group pretest-posttest design met aanvullende vergelijkingen met data uit hoofdstuk 4, wordt de verschuiving van zorg van patiënten met stabiele diabetes type 2 van huisarts naar verpleegkundig specialist (verticale substitutie) in hoofdstuk 5 bestudeerd. Met enkele kleine aanpassingen is gebruik gemaakt van het protocol uit het model van hoofdstuk 4. Zo lag het aantal door de verpleegkundig specialist te verrichten consulten niet vast, maar de jaarlijkse controle door de huisarts wel. Wederom treedt een statistisch significante verbetering op in glycaemische controle (met–0.3% tot 7.7%; n=158) als ook in gezondheidstoestand, zelfzorggedrag, kennis over diabetes, en patiënttevredenheid. Patiënten rapporteerden een statistisch significante toename in het aantal consulten met zorgverleners. Hoofdstuk 4 en 5 laten zien dat op substitutie gebaseerde zorgnetwerken, waarin traditioneel door de arts vervulde rollen en taken worden overgenomen door de verpleegkundig specialist, in termen van patiëntuitkomsten resulteren in equivalente kwaliteit van zorg en verbeteringen in glycaemische controle.

Tabel 1
Hoofdkenmerken van de studies gepresenteerd in hoofdstuk 4, 5, and 6

Hoofd-stuk	ziekte	study design	wijze van zorgverlening		aantal patiënten		RR[c] / CR[d]
			IG[a]	RG[b]	IG[a]	RG[b]	
4	diabetes type 2	non- equivalent control group	traditionele zorg door verpleegkundig specialist aan poli-patiënten in de huisartsenpraktijk	traditionele zorg door endocrinoloog aan patiënten op de polikliniek	52[e]	47	64 / 55
5	diabetes type 2	pretest- posttest	traditionele zorg door verpleegkundig specialist aan patiënten in de huisartsenpraktijk	[traditionele zorg door endocrinoloog aan patiënten op de polikliniek]	175 [44[e]]	[47]	54 / 59 [55 / 47]
6	COPD	randomised controlled trial	traditionele zorg door verpleegkundig specialist aan patiënten op de polikliniek	traditionele zorg door longarts aan patiënten op de polikliniek	91	83	93 / 85

[a]IG=interventie groep; [b]RG=referentie groep; [c]RR=response rate; [d]CR=completion rate; [e]interventie *sub*groep zonder de patiënten met orale hypoglycaemische medicatie en/of alleen op dieet; [ ] additionele vergelijkingen.

Tabel 2
Statistisch significante uitkomsten van studies gepresenteerd in hoofdstuk 4, 5, en 6

Hoofd-stuk	ziekte	klinische parameters	kwaliteit van leven	zelfzorggedrag/ kennis	patiënt tevredenheid	totale medische consumptie
4	diabetes type 2	+	=	= / =	=	=
5	diabetes type 2	+ [=]	= [=]	+ / + [= /=]	= [=]	* [=]
6	COPD	=	=	+ / +	+	*[a]

+ statistisch significante verbetering; * statistisch significante verhoging; = equivalente uitkomst; [ ] additionele vergelijkingen; [a] gebaseerd op registratie door zorgverlener, geen verschil gerapporteerd door patiënten

Hoofdstuk 6 en 7 beschrijven interventies waarin de verpleegkundig specialist een centrale rol vervult in de zorg aan mnsen met COPD. De effecten op kwaliteit van zorg, wanneer taken in de zorg voor poliklinisch behandelde patiënten met stabiele COPD worden verschoven van longarts naar verpleegkundig specialist (verticale substitutie), worden geëvalueerd in hoofdstuk 6. Zorgverlening vindt plaats volgens een protocol op de polikliniek van een algemeen ziekenhuis door de verpleegkundig specialist, welke het hoogste verpleegkundig kwalificatieniveau heeft en gespecialiseerd is in COPD. Door gebruik te maken van een randomised controlled trial blijkt na 9 maanden dat de groepen (interventie groep n=91, controle groep n=83) vergelijkbaar zijn voor klinische parameters, gezondheidstoestand, kennis over COPD, en zelfzorggedrag, terwijl patiënten die zorg ontvangen van de verpleegkundig specialist meer consultaties krijgen en, eveneens statistisch significant, een hogere tevredenheid over de zorgverlening rapporteren. De conclusie luidt dat het verschuiven van zorg voor poliklinische behandelde patiënten met COPD door een protocollair werkende verpleegkundige, in termen van patiëntuitkomsten, een gerechtvaardigd alternatief is voor zorgverlening door een longarts.

Hoofdstuk 7 beschrijft hoe patiënten, die hun huisarts bezochten voor een niet aan een longaandoening gerelateerde reden en die verklaarden (ex)roker te zijn, een diagnostische longfunctie test hebben ondergaan die werd uitgevoerd door een longverpleegkundige in de huisartsenpraktijk. COPD werd vastgesteld onder 7.4% van de risicopatiënten (n=231), terwijl de betrouwbaarheid van de vroege opsporing door niet-artsen in de huisartsenpraktijk werd bevestigd door de voorspellende waardes van de variabelen pakjaren en kortademigheid onder deze patiënten. Geconcludeerd wordt dat de diensten van de verpleegkundig specialist ook waardevol zijn in de vroege opsporing van COPD.

In het afsluitende hoofdstuk wordt, na een korte samenvatting van de voornaamste bevindingen van de studies in dit proefschrift, ingegaan op de methodologische beperkingen en worden aanbevelingen gedaan voor beleid en verder onderzoek. Voor het evalueren van de effecten van zorgnetwerken voor chronisch zieken met een centrale rol voor de verpleegkundig specialist is gebruik gemaakt van verschillende onderzoeksdesigns. Het, in verschillende mate, optreden van diverse vormen van bias is derhalve onvermijdelijk, maar levert desondanks belangrijke inzichten op. Het verschuiven van zorg voor chronisch zieken van arts naar verpleegkundig specialist is in termen van patiëntuitkomsten gerechtvaardigd, maar dient ook op andere gebieden, zoals juridisch en economisch, te worden gerechtvaardigd. Verder onderzoek, met bijzondere aandacht voor de methodologie, is nodig om optimaal gebruik te kunnen maken van de diensten van de verpleegkundig specialist in de zorg voor het toenemend aantal chronisch zieken.

DANKWOORD

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CURRICULUM VITAE

Bert Vrijhoef was born on March 20, 1971 in Roosendaal. After the first two years of primary school in the small village called Huijbergen, together with his parents and his brother he moved back to Roosendaal where he finished primary school and high school. In 1989 he decided to start working as an assistant-accountant. One year later, just before his father died, he started to study Health Policy and Management at the Erasmus University in Rotterdam. Before his graduation, he participated as a student researcher at the Royal College of Surgeons in Dublin, Ireland. In three months he wrote a chapter of an advisory report for the Irish government on the prevention of coronary heart disease. Back from Dublin he finished his master thesis on the cost-effectiveness of fundusphotography and before he applied for his diploma he worked for about half a year as a research associate for the board of the Foundation of General Practitioners Laboratory in Breda (Stichting Huisartsen Laboratorium).

After his graduation at the Erasmus University in June 1996, he started to work at the Department of Medical Sociology of the University of Maastricht on the PhD-project 'Care-networks for chronically ill: a central role for the nurse specialist.' He was involved in teaching and was a member of the executive board of the department and of the interfaculty committee on science. During the second year of his PhD-project he started to work part-time in a private research office with two business partners, first in Rotterdam and later in Amsterdam. One and a half year later they decided to end their successful office and to specialise each in their own field of professional interest.

In June 2000 he started working as a researcher at the Office for Medical Technology Assessment at the University Hospital Groningen. Three months later he was appointed as a post-doc researcher at the Department of Health Sciences, University of Maastricht. With professor Spreeuwenberg and professor Van Merode he started working on the new research programme 'Health Technology Assessment of disease management.'

Since January 2001 he combines this appointment with one at the Department of Integrated Care at the university hospital Maastricht. At this moment he is, as a scientific researcher, involved in numerous projects in the area of the effectiveness and efficiency of integrated care and disease management. In addition, since July 2001 he is chair of the research group of the Association of Diabetes Nurses (Eerste Associatie van Diabetes Verpleegkundigen (EADV), Nieuwegein).